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Centre d'Esclerosi Múltiple de Catalunya

Ofatumumab en esclerosis múltiple

Jaume Sastre-Garriga @J_SastreGarriga

Servei de Neurologia

Centre d'Esclerosi Múltiple de Catalunya – Cemcat

Hospital Universitari Vall d'Hebron, Barcelona

Vall d'Hebron Barcelona Campus Hospitalari

fem FUNDACIÓ ESCLEROSI MÚLTIPLE

Disclosures

- I am a clinical neurologist
- Editor-in-chief at the **Multiple Sclerosis Journal**
- Over the last 12 months, I have participated as speaker in events organized by Merck, Cobel Darou, Roche, and BMS
- Presently serving as co-chair of **MAGNIMS**
- Member of the **ECTRIMS** Executive Board

Magnims
Magnetic Resonance Imaging in Multiple Sclerosis

ECTRIMS
EUROPEAN COMMITTEE FOR TREATMENT AND RESEARCH IN MULTIPLE SCLEROSIS

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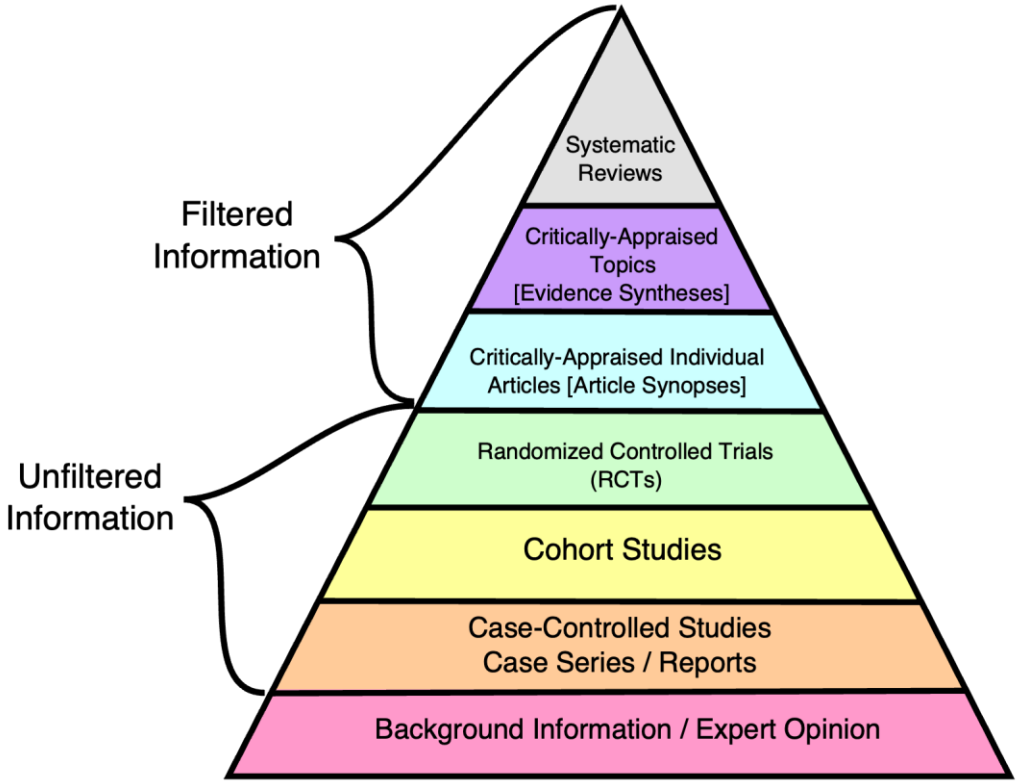
Evidence



Better level of evidence
Lower individual information
Lower day to day applicability

Worse level of evidence
More individual information
Increased day to day applicability

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Best level of evidence

Hazardous journeys

Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon C S Smith, Jill P Pell

Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials

What is already known about this topic

Parachutes are widely used to prevent death and major injury after gravitational challenge

Parachute use is associated with adverse effects due to failure of the intervention and iatrogenic injury

Studies of free fall do not show 100% mortality

What this study adds

No randomised controlled trials of parachute use have been undertaken

The basis for parachute use is purely observational, and its apparent efficacy could potentially be explained by a "healthy cohort" effect

Individuals who insist that all interventions need to be validated by a randomised controlled trial need to come down to earth with a bump

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Smith and Pell, BMJ 2003

Best level of evidence

Parachute use to prevent death and major trauma when jumping from aircraft: randomized controlled trial

Robert W Yeh,[1] Linda R Valsdottir,[1] Michael W Yeh,[2] Changyu Shen,[1] Daniel B Kramer,[1] Jordan B Strom,[1] Eric A Secemsky,[1] Joanne L Healy,[1] Robert M Domeier,[3] Dhruv S Kazi,[1] Brahmajee K Nallamothu[4] On behalf of the PARACHUTE Investigators

Table 3 Event rates for primary and secondary endpoints. Values are numbers (percentages) unless stated otherwise

Endpoint	Parachute	Control	Mean difference (95% CI)	P value
On impact				
Death or major traumatic injury	0 (0)	0 (0)	0	>0.9
Mean (SD) Injury Severity Score	0 (0)	0 (0)	0	>0.9
30 days after impact				
Death or major traumatic injury	0 (0)	0 (0)	0	>0.9
Mean (SD) Injury Severity Score	0 (0)	0 (0)	0	>0.9
Health status				
Mean (SD) Short Form Health Survey score	43.9 (1.8)	44.0 (2.4)	0.1 (−2.0 to 2.2)	0.9
Mean (SD) physical health subscore	19.6 (0.7)	19.7 (0.5)	0.04 (−0.5 to 0.6)	0.9
Mean (SD) mental health subscore	24.3 (1.3)	24.3 (2.1)	0.08 (−1.6 to 1.8)	0.9

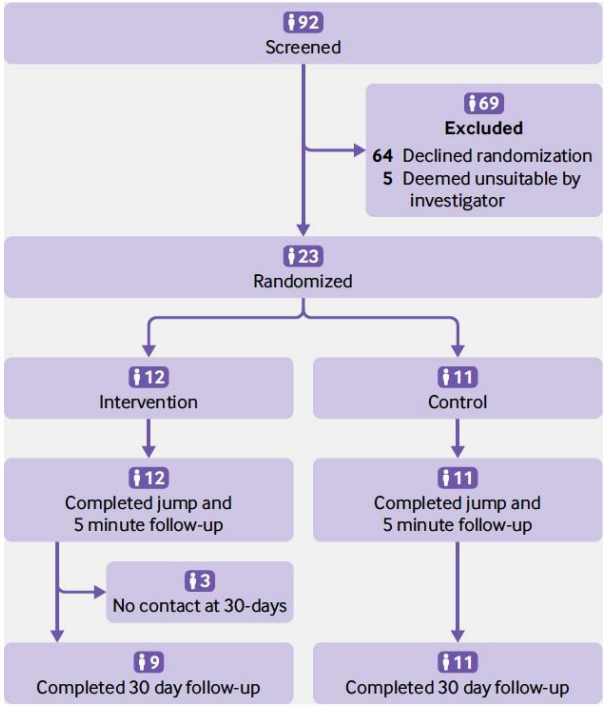

Fig 1 | Study flow diagram

PARACHUTE investigators, BMJ 2018

Best level of evidence

Parachute use to prevent death and major trauma when jumping from aircraft: randomized controlled trial

Robert W Yeh,[1] Linda R Valsdottir,[1] Michael W Yeh,[2] Changyu Shen,[1] Daniel B Kramer,[1] Jordan B Strom,[1] Eric A Secemsky,[1] Joanne L Healy,[1] Robert M Domeier,[3] Dhruv S Kazi,[1] Brahmajee K Nallamothu[4] On behalf of the PARACHUTE Investigators

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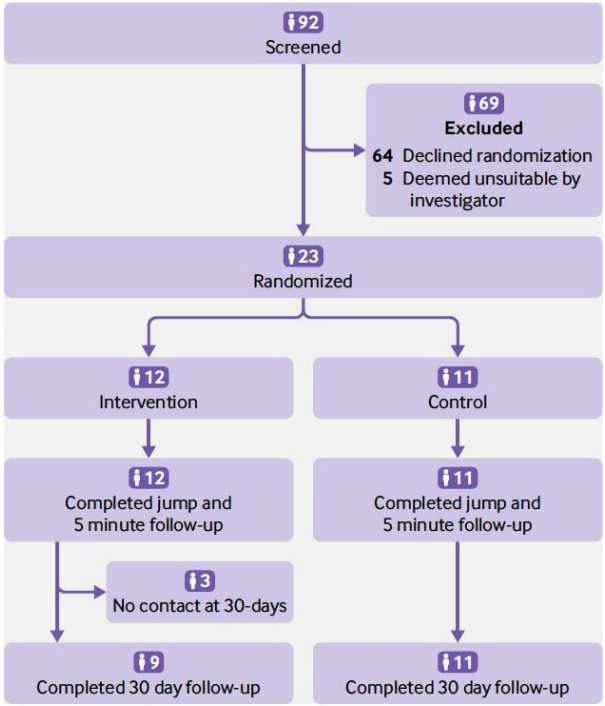

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Fig 2 | Representative study participant jumping from aircraft with an empty backpack. This individual did not incur death or major injury upon impact with the ground

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PARACHUTE investigators, BMJ 2018

Randomized clinical trials: IFNbeta-1b in SPMS

EUSPMS - Lancet 1998

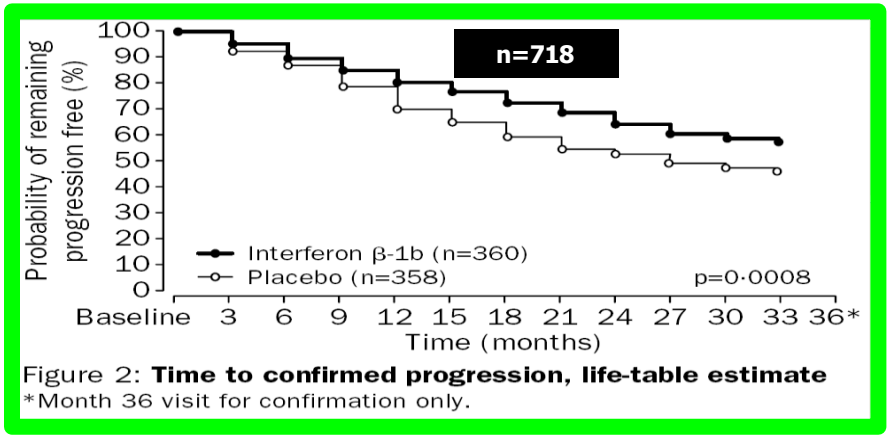
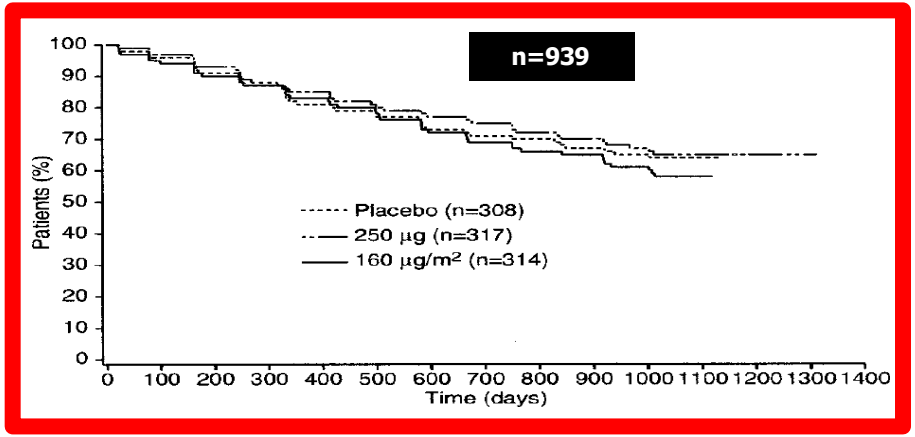


Figure 2: **Time to confirmed progression, life-table estimate**
*Month 36 visit for confirmation only.

NASPMS - Neurology 2004



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Randomized clinical trials: Natalizumab discontinuation studies

tation of 3.8 years). The median annualized number of active T2 lesions was increased in the postwithdrawal interval compared with the pretreatment interval (10.32 [interquartile range (IQR) 2.71 to 16.42] vs 3.43 [IQR 0.99 to 6.96], $p = 0.014$). Descriptive comparisons suggested no effect of age, sex, disease duration, MRI lesion load, or being enrolled in AFFIRM vs SENTINEL. The increase in disease activity was much more pronounced in placebo/natalizumab (from 2.24 pre treatment to 10.37 post withdrawal) patients vs natalizumab/natalizumab (from 3.47 pre treatment to 4.81 post withdrawal) patients. For the total group of patients, the median annual relapse rate was 1.15 in the pretreatment MRI interval and 0.73 in the postwithdrawal interval.

M.M. Vellinga, MD
J.A. Castelijns, MD, PhD
F. Barkhof, MD, PhD
B.M.J. Uitdehaag, MD, PhD
C.H. Polman, MD, PhD

POSTWITHDRAWAL REBOUND INCREASE IN T2 LESIONAL ACTIVITY IN NATALIZUMAB-TREATED MS PATIENTS

Natalizumab significantly reduces relapse rate, disability progression, and lesion development in relapsing multiple sclerosis (MS).[1,2] Dosing was suspended when cases of progressive multifocal

would help clarify this question. But given the currently available data, there appears to be no concern for rebound in patients receiving chronic natalizumab therapy (i.e., ≥6 months) or patients who develop neutralizing antibodies.

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Vellinga et al., Neurology 2008; Fox & Kappos, Neurology 2008

Biases of observational studies

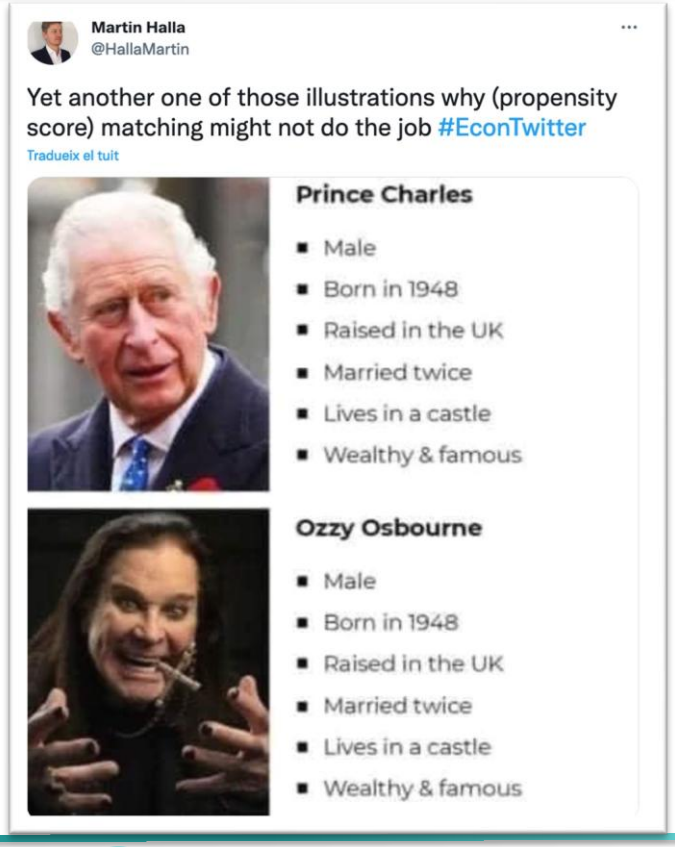
Table 1. Classes of bias in observational data.

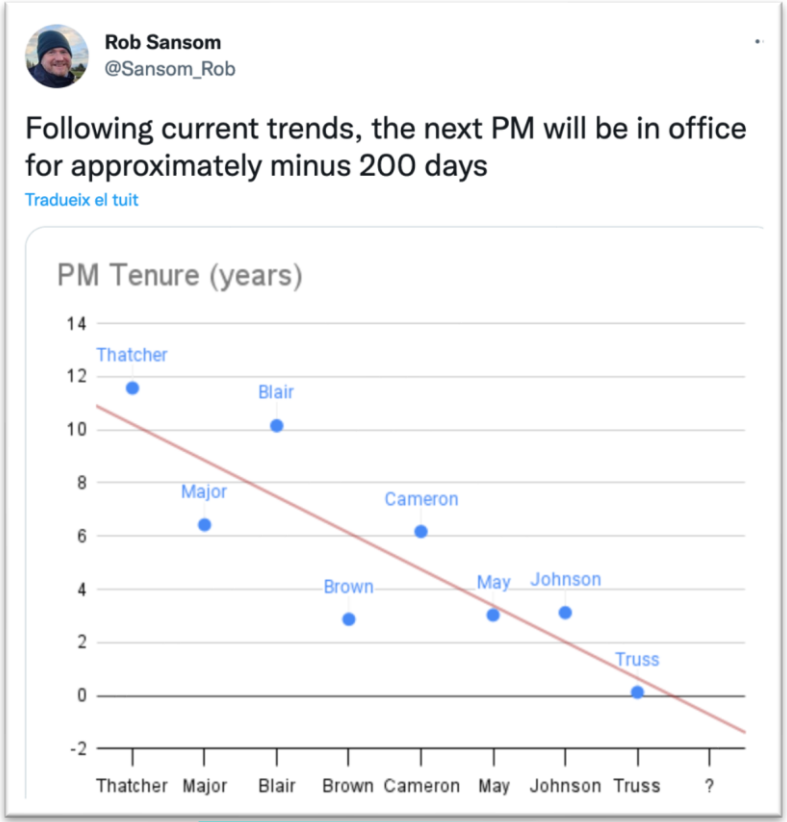
Bias	Origin	Mitigation strategy
Indication bias	Non-random treatment exposure	Multivariable adjusted models, matching
Attrition bias	Between-group difference in follow-up duration	Pairwise censoring
Detection bias	Differences in follow-up protocols	Models adjusted for follow-up density (e.g. frequency of visits or MRI scans)
Immortal time bias	Systematic differences in the definitions of study entry	Modelling time-dependent covariates
Will Rogers phenomenon	Changing diagnostic criteria	Sensitivity analyses excluding historical cohorts
Recall bias	Systematic differences in the proportion of retrospective data	Sensitivity analyses using only prospectively recorded data
Selection bias	Preferential inclusion of subpopulations in registries	Sensitivity analysis using only population-based cohorts
Unidentified bias	Missing information for confounders of disease outcomes	Estimation of the robustness to hidden bias (e.g. Rosenbaum bounds)

MRI: magnetic resonance imaging.

Kalincik & Butzkueven Mult Scler J 2016

Beware of mitigation strategies





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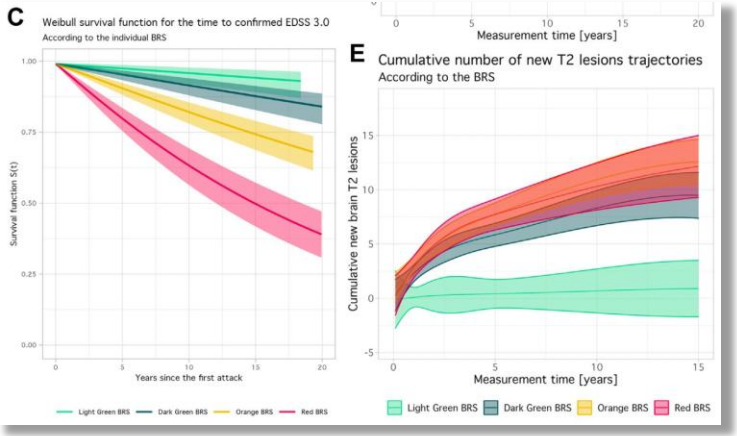
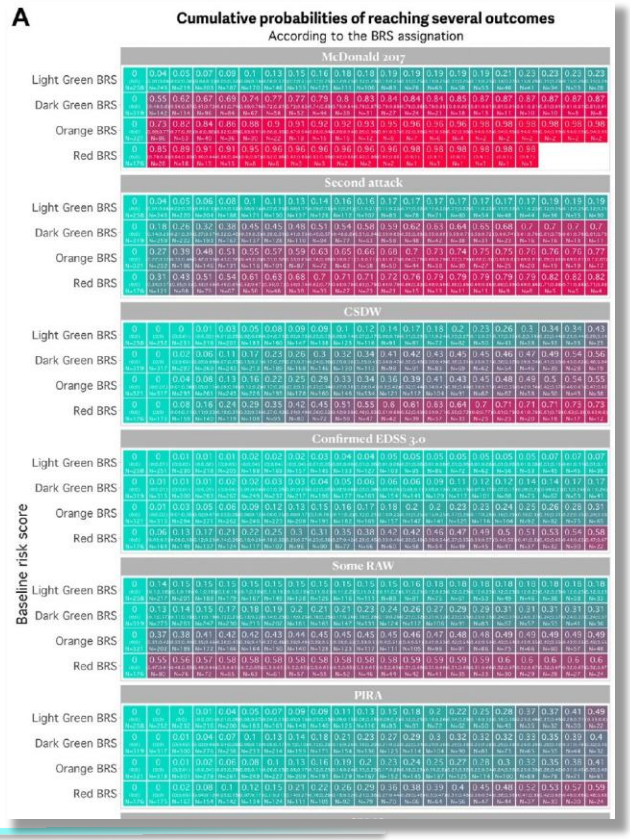
Predicting disease course

The Barcelona baseline risk score to predict long-term prognosis after a first demyelinating event: a prospective observational study

Carmen Tur,[a,*] Pere Carbonell-Mirabent,[a] Susana Otero-Romero,[a] Álvaro Cobo-Calvo,[a] María Jesús Arévalo,[a] Helena Ariño,[a] Georgina Arrambide,[a] Cristina Auger,[b,d] René Carvajal,[a] Joaquín Castilló,[a] Manuel Comabella,[a] Ingrid Galán,[a] Luciana Midaglia,[a] Carlos Nos,[a] Agustín Pappolla,[a] Deborah Pareto,[b,d] Jordi Río,[a] Breogán Rodríguez-Acevedo,[a] Estibaliz Saez de Gordoa,[b,d] Ángela Vidal-Jordana,[a] Ana Zabalza,[a] Jaume Sastre-Garriga,[a] Àlex Rovira,[b,d] Xavier Montalban,[a,c,e] and Mar Tintoré[a,c,e]





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Tur et al, et al. Lancet Regional Health 2025

Treatment choices

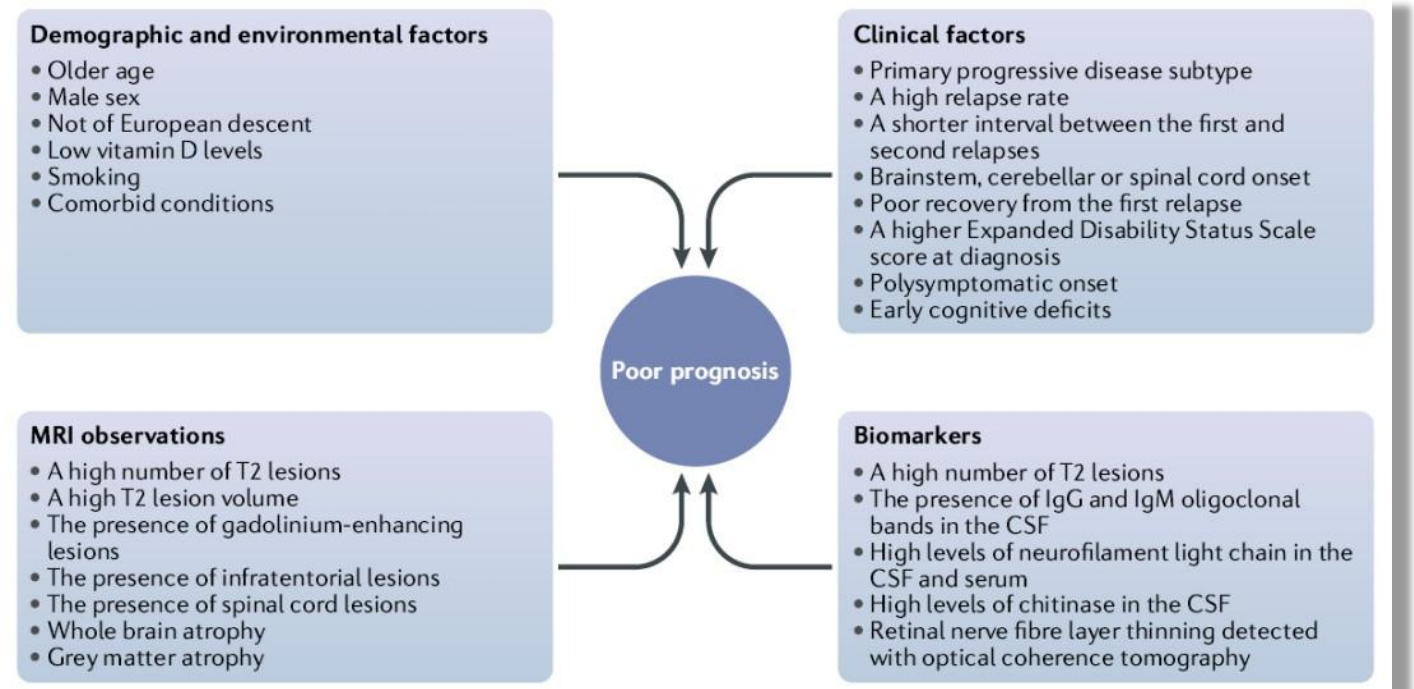

Fig. 1 | **Predictors of a poor prognosis in multiple sclerosis.** The demographic and environmental factors, clinical factors, MRI observations and biomarkers that have been associated with a poor prognosis in multiple sclerosis are listed. CSF, cerebrospinal fluid; IgG, immunoglobulin G; IgM, immunoglobulin M.

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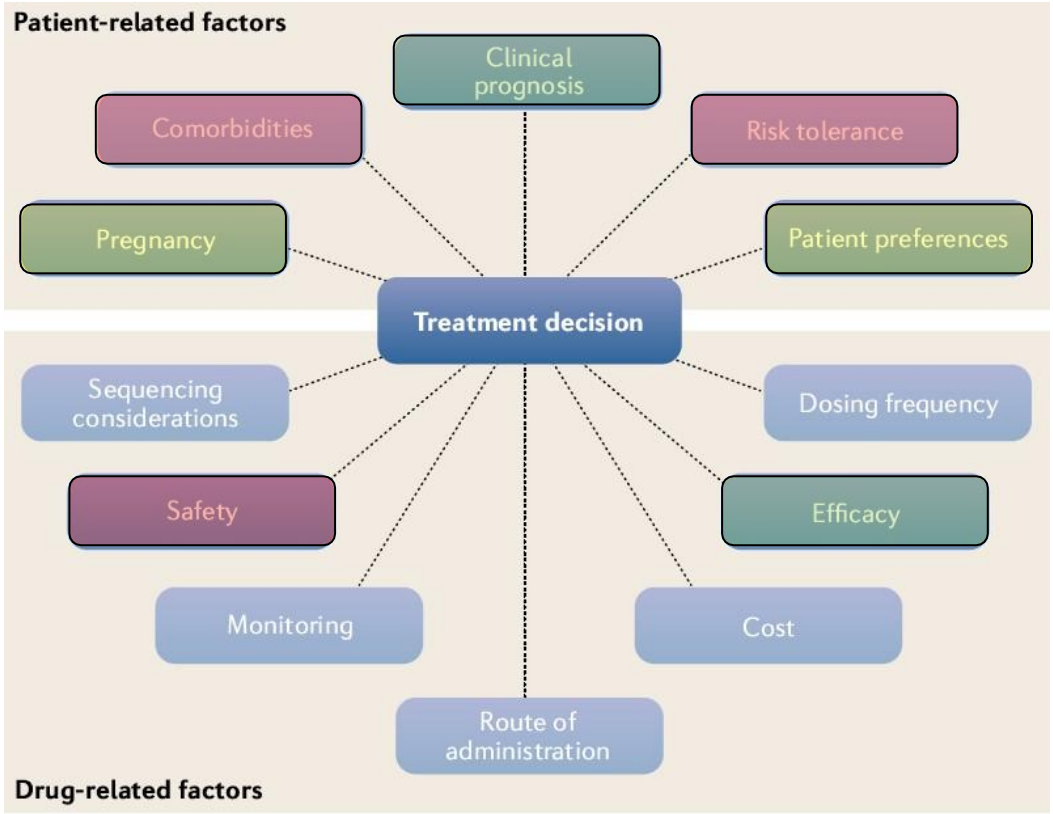
Rotstein D and Montalban X, Nat Rev Neurol 2019

Treatment choices



Rotstein D & Montalban X. Nat Rev Neurol 2019

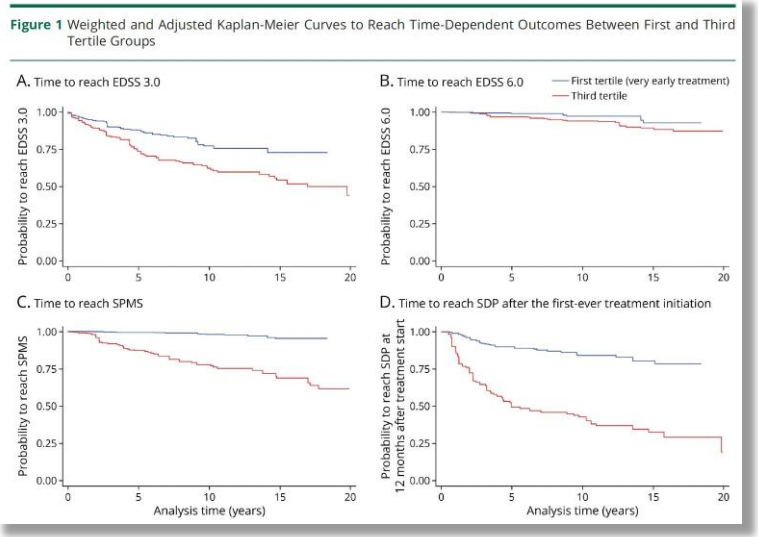
Treatment choices, but the earlier the better

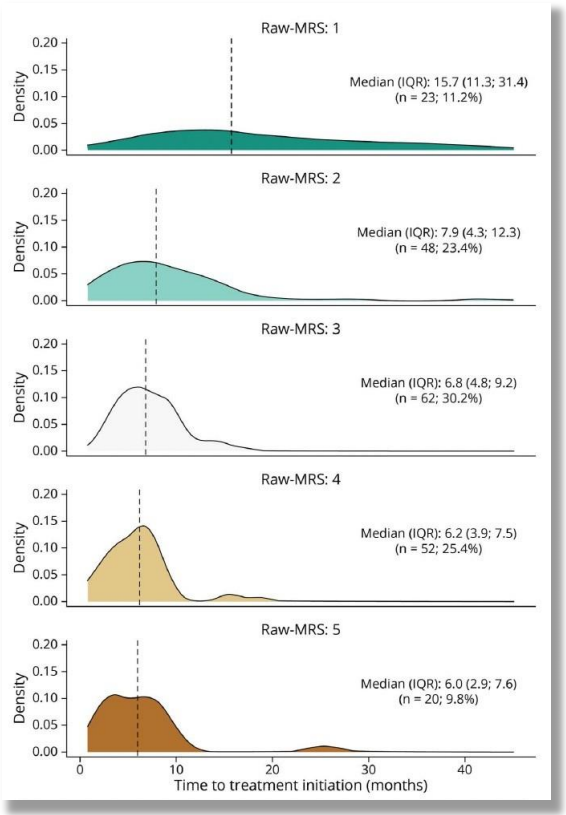
RESEARCH ARTICLE

Association of Very Early Treatment Initiation With the Risk of Long-term Disability in Patients With a First Demyelinating Event

Alvaro Cobo-Calvo, MD, PhD, Carmen Tur, MD, PhD, Susana Otero-Romero, MD, PhD, Pere Carbonell-Mirabent, MSc, Mariano Ruiz, MD, Agustin Pappolla, MD, Javier Villacieros Alvarez, MD, Angela Vidal-Jordana, MD, PhD, Georgina Arrambide, MD, PhD, Joaquín Castilló, MD, Ingrid Galan, MD, Marta Rodríguez Barranco, DM, Luciana Soledad Midaglia, MD, Carlos Nos, MD, PhD, Breogan Rodriguez Acevedo, MD, Ana Zabalza de Torres, MD, Neus Mongay, MD, Jordi Rio, MD, PhD, Manuel Comabella, MD, PhD, Cristina Auger, MD, Jaume Sastre-Garriga, MS, PhD, Alex Rovira, MD, Mar Tintore, MD, PhD,* and Xavier Montalban, MD, PhD*

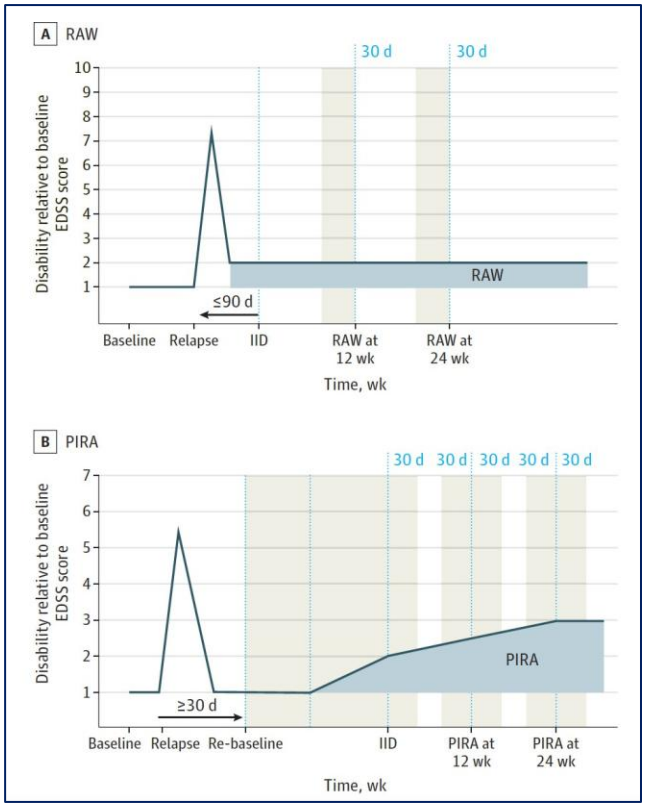
Correspondence
Dr. Cobo-Calvo
acobo@cem-cat.org





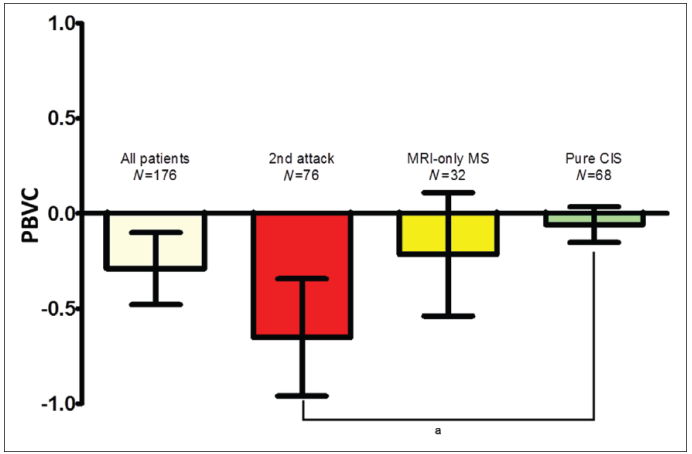
Cobo-Calvo et al, Neurology 2023

Early, as progression starts from onset



Progression independent of relapses (PIRA) early in the disease course

Progressive disease since relapsing MS onset



Brain atrophy in the first months after a CIS

Kappos L, et al. JAMA Neurol. 2020; Pérez-Miralles F, Mult Scler 2013

As early as RIS

Secondary Prevention in Radiologically Isolated Syndromes and Prodromal Stages of Multiple Sclerosis

Maria Pia Amato[1,2], Nicola De Stefano[3], Matilde Inglese[4,5], Emanuele Morena[6], Giovanni Ristori[6,7], Marco Salvetti[6,8] and Maria Trojano[9] on behalf of the Italian Group for Radiologically Isolated Syndromes and Prodromal Stages of MS*

Contents lists available at ScienceDirect

Multiple Sclerosis and Related Disorders

journal homepage: www.elsevier.com/locate/msard

The CELLO trial: Protocol of a planned phase 4 study to assess the efficacy of Ocrelizumab in patients with radiologically isolated syndrome

Erin E. Longbrake[a,*], Le H. Hua[b], Ellen M. Mowry[c], Susan A. Gauthier[d], Enrique Alvarez[e], Pei[g], Jessica Priest[g], Catarina Raposo[g], David A. Hafler[a],

ECTRIMS 2022
38th Congress of the European Committee for Treatment and Research in Multiple Sclerosis
27th Annual RIMS Conference
26 – 28 October 2022
Amsterdam, The Netherlands

O179

Multi-center, randomized, double-blinded assessment of dimethyl fumarate in extending the time to a first clinical demyelinating event in radiologically isolated syndrome (ARISE)

D.T. Okuda[1], O. Kantarci[2], C. Lebrun-Frénay[3], M.P. Sormani[4], C.J. Azevedo[5], F. Bovis[6], L.H. Hua[7], L. Amezcua[5], E.M. Mowry[8], C. Hotermans[9], J. Mendoza[10],

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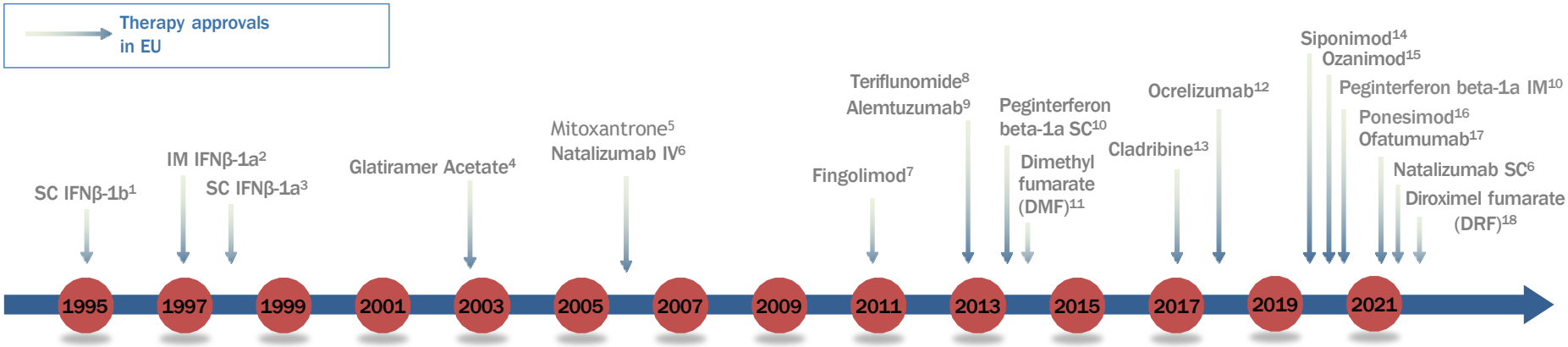
Amato MP, et al. Front Neurol 2021; Longbrake E, et al. MSRD 2022

What DMT?



BTK, Bruton's tyrosine kinase; **GA**, glatiramer acetate; **IFNβ**, interferon beta; **IM**, intramuscular; **MS**, multiple sclerosis; **SC**, subcutaneous. **1.** Betaferon (interferon beta-1b). EU Summary of Product Characteristics (SmPC); Dec 2020; **2**. Avonex (interferon beta-1a). EU SmPC; Mar 2021; **3**. Rebif (interferon beta-1a). EU SmPC; Jan 2021; **4**. Copaxone (glatiramer acetate). UK SmPC; Aug 2021; **5**. Novantrone (mitoxantrone). UK SmPC. Feb 2021; **6**. Tysabri (natalizumab). EU SmPC; Aug 2021; **7**. Gilenya (fingolimod). EU SmPC; Aug 2021; **8**. Aubagio (teriflunomide). EU SmPC; Aug 2021; **9**. Lemtrada (alemtuzumab). EU SmPC; Aug 2021; **10**. Plegridy (peginterferon beta-1a). EU SmPC; Mar 2021; **11**. Tecfidera (dimethyl fumarate). EU SmPC; Apr 2021; **12**. Ocrevus (ocrelizumab). EU SmPC; May 2021; **13**. Mavenclad (cladribine). EU SmPC; Apr 2021; **14**. Mayzent (siponimod). EU SmPC; Jan 2021; **15**. Zeposia (ozanimod). EU SmPC; Oct 2020; **16.** Ponvory (ponesimod). EU SmPC; June 2021; **17**. Kesimpta (ofatumumab). EU SmPC; June 2021; **18.** Vumerity (diroximel fumarate) EU SmPC; November 2021; **19**. Dolgin E. Nature Biotechnology. 2021;39:3-5; **20**. Biogen press release. Available at: https://investors.biogen.com/news-releases/news-release-details/biogen-and-innocare-announce-license-and-collaboration-agreement. Accessed: Aug 2021.

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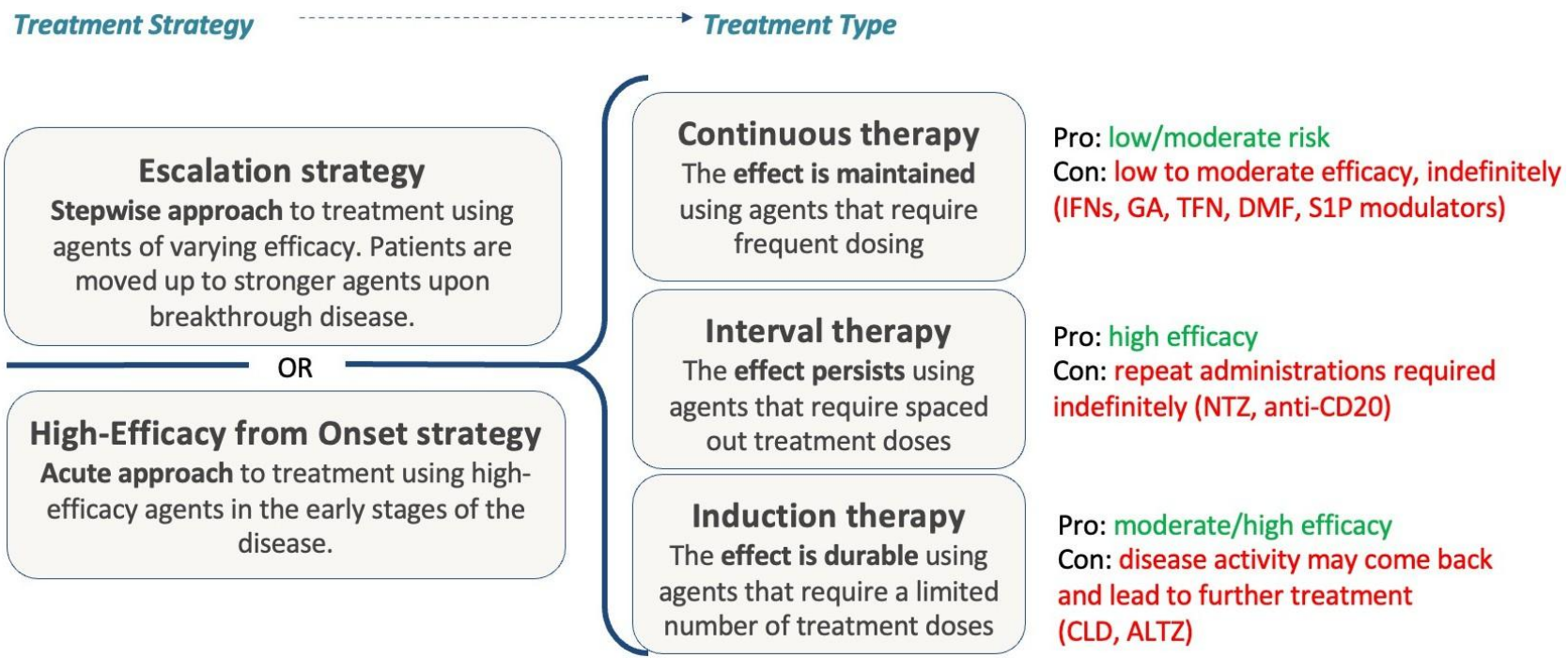
Slide courtesy of Prof. Xavier Montalban

What strategy?



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Slide courtesy of Prof. Xavier Montalban

What strategy?

Original Investigation FREE

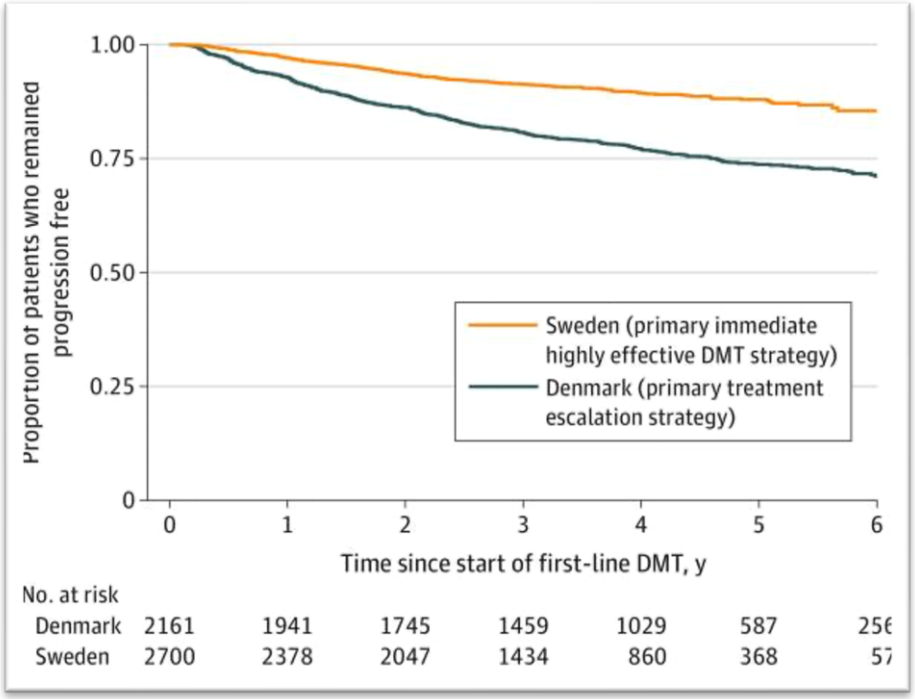
August 16, 2021

Treatment Escalation vs Immediate Initiation of Highly Effective Treatment for Patients With Relapsing-Remitting Multiple Sclerosis

Data From 2 Different National Strategies

Tim Spelman, PhD, MD[1]; Melinda Magyari, PhD, MD[2,3,4]; Fredrik Piehl, PhD, MD[1]; et al

The Swedish treatment strategy was associated with a **29% reduction in the rate of postbaseline 24-week CDW** relative to the Danish treatment strategy (inverse probability of treatment weighting hazard ratio [HR], 0.71; 95% CI, 0.57-0.90; *P* = .004)



Spelman T, et al. JAMA Neurol 2021

What strategy?

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	Danish	Swedish
First treatment[e]		
Interferon beta-1a	643 (29.8)	616 (22.8)
Interferon beta-1b	6 (0.3)	176 (6.5)
Glatiramer acetate	128 (5.9)	128 (4.7)
Dimethyl fumarate	280 (13.0)	615 (22.8)
Rituximab	3 (0.1)	484 (17.9)
Natalizumab	104 (4.8)	299 (11.1)
Fingolimod	58 (2.7)	148 (5.5)
Pegylated interferon beta-1a	30 (1.4)	86 (3.2)
Teriflunomide	907 (42.0)	64 (2.4)
Other	2 (0.1)	84 (3.1)

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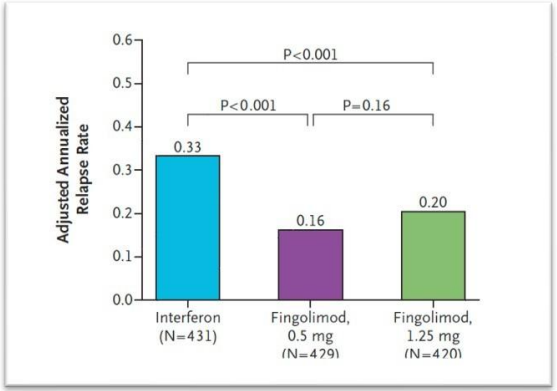
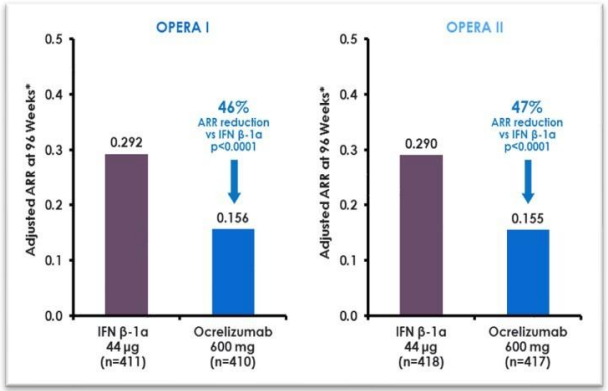
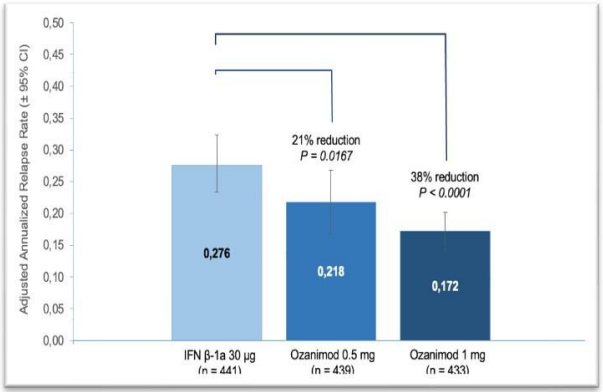
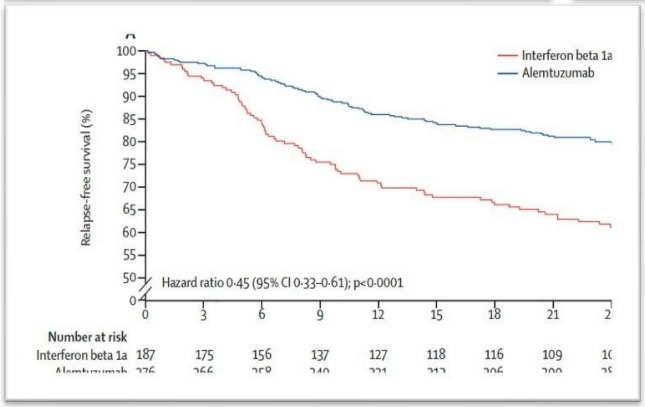
Spelman T, et al. JAMA Neurol 2021

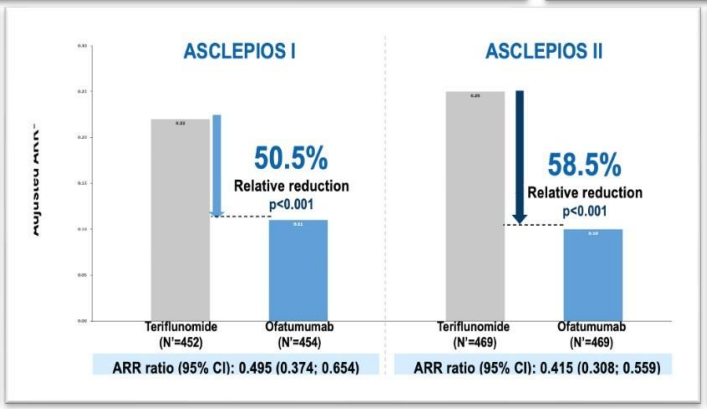
Randomized controlled trials: relapsing MS

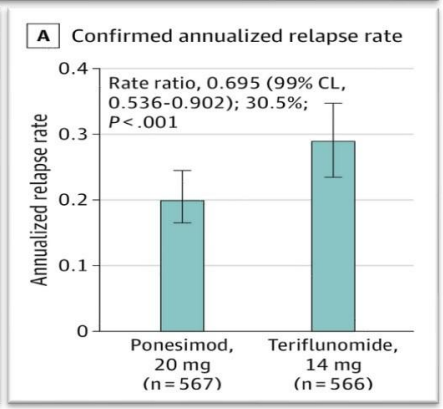










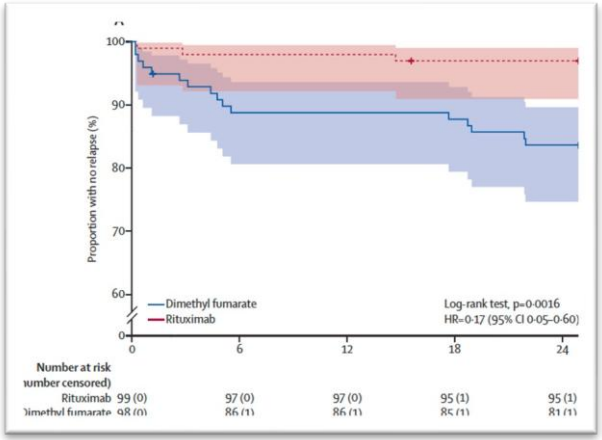


Cohen J, et al. NEJM 2010; Cohen J, et al. The Lancet 2012; Hauser S, et al. NEJM 2016; Hauser S, et al. NEJM 2020

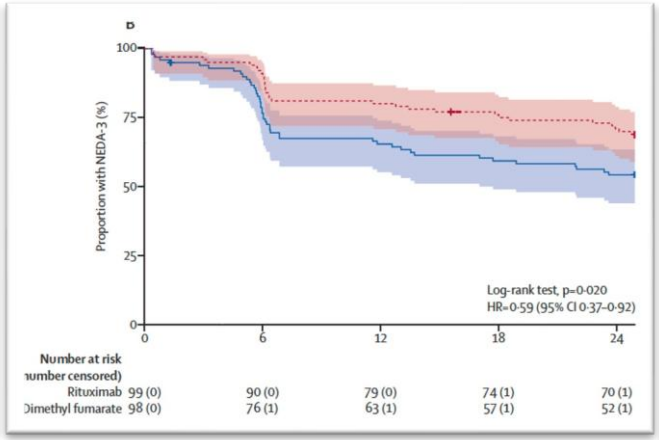
Randomized controlled trials: relapsing MS

Safety and efficacy of rituximab versus dimethyl fumarate in patients with relapsing-remitting multiple sclerosis or clinically isolated syndrome in Sweden: a rater-blinded, phase 3, randomised controlled trial

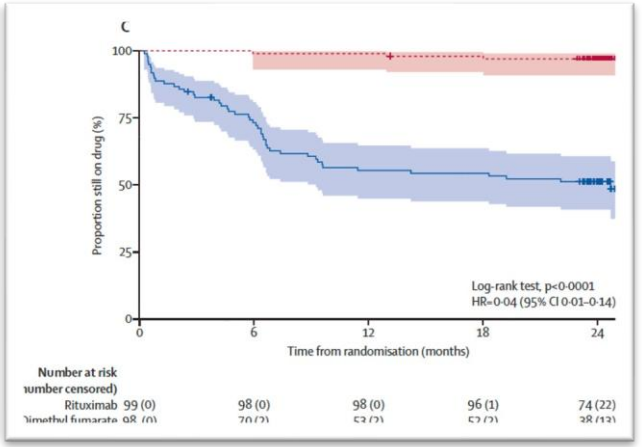
Anders Svenningsson, Thomas Frisell, Joachim Burman, Jonatan Salzer, Katharina Fink, Susanna Hallberg, Joakim Hambraeus, Markus Axelsson, Faiez Al Nimer, Peter Sundström, Martin Gunnarsson, Rune Johansson, Johan Mellergård, Igal Rosenstein, Ahmad Ayad, Irina Sjöblom, Anette Risedal, Pierre de Flon, Eric Gilland, Jonas Lindeberg, Fadi Shayket, Fredrik Piehl, Jan Lycke



Relapse free



NEDA-3



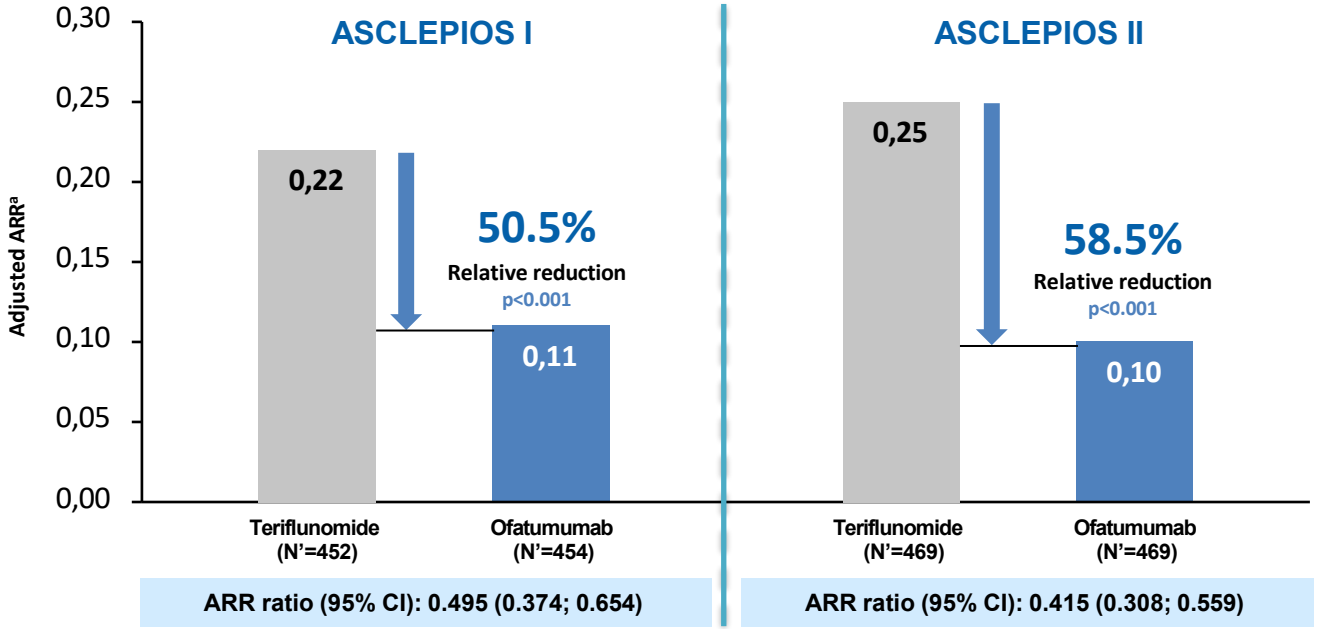
Patients on drug

Cemcat

Svenningsson A, et al. Lancet Neurol 2022

Ofatumumab: evidence from clinical trials

Primary outcome: annualized relapse rate



Full analysis set. Primary endpoint. [a]Negative binomial regression model. ARR, annualized relapse rate; CI, confidence interval; N', total number of patients included in the analysis.

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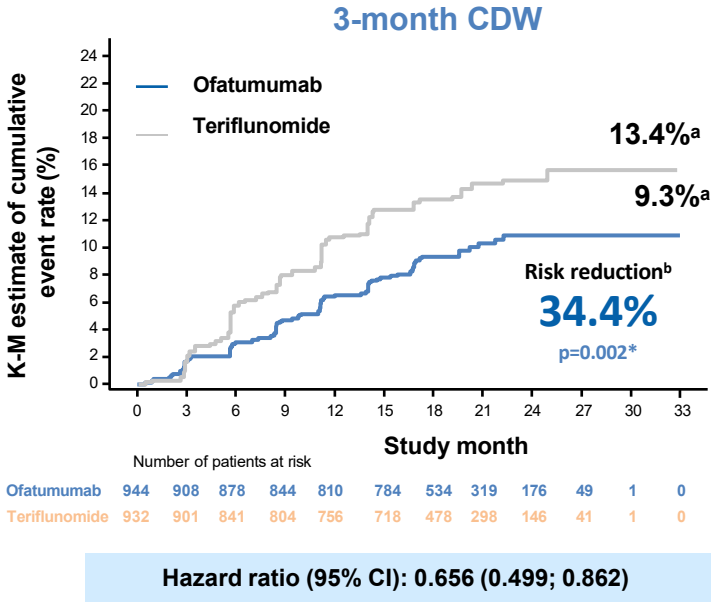
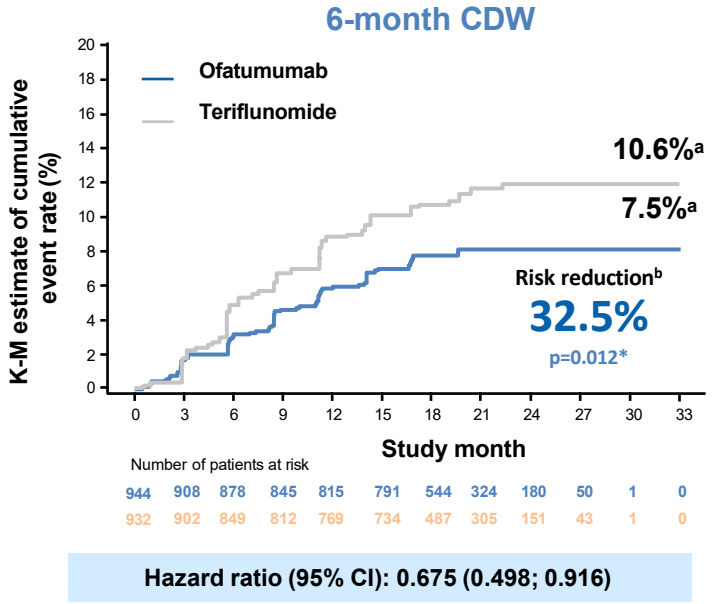
Hauser SL et al. N Engl J Med. 2020;383:546-557.

Ofatumumab: evidence from clinical trials

3- and 6-month confirmed disease worsening. Pre-specified pooled analysis



Hazard ratio (95% CI): 0.656 (0.499; 0.862)



Hazard ratio (95% CI): 0.675 (0.498; 0.916)

Full analysis set. Secondary endpoints. *Indicates statistical significance (two-sided) at the 0.04875 level. [a]Proportion of patients with 3- or 6-month CDW, [b]Cox regression model. CDW, confirmed disability worsening; CI, confidence interval; K-M, Kaplan–Meier

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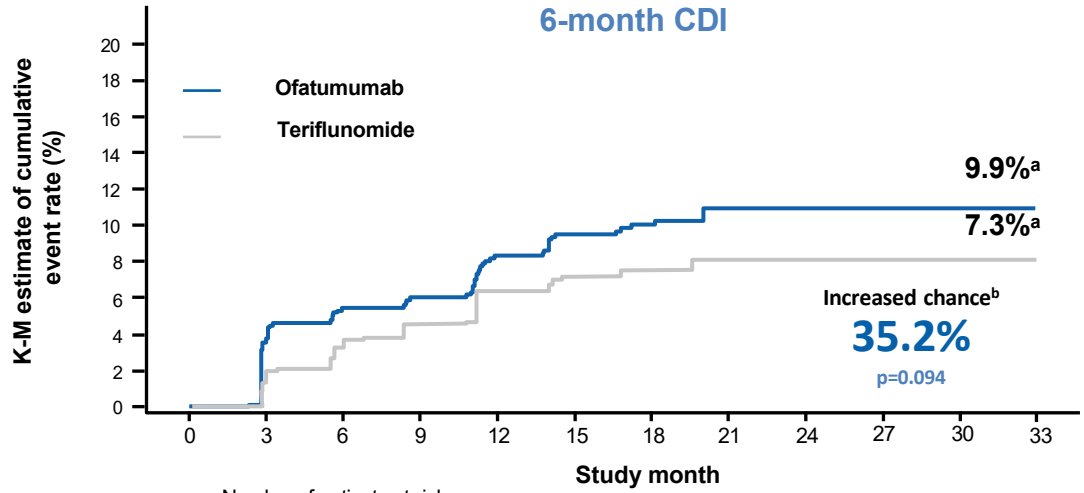
Hauser SL et al. N Engl J Med. 2020;383:546-557.

Ofatumumab: evidence from clinical trials

6-month confirmed disease improvement. Pre-specified pooled analysis



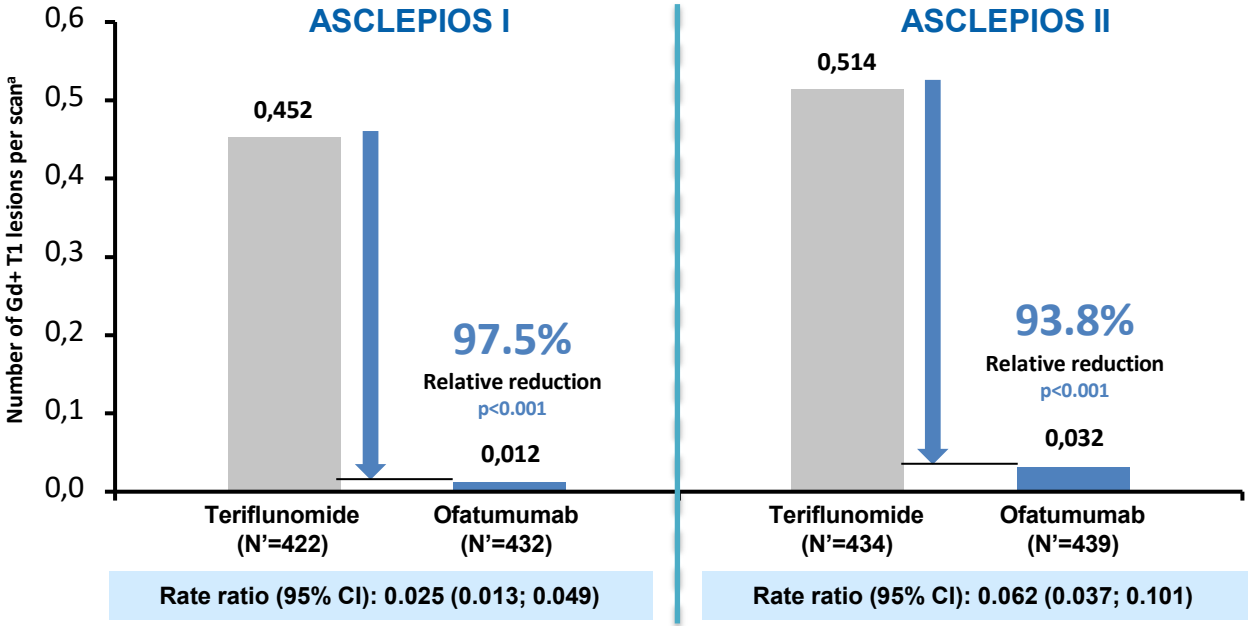
Full analysis set. Secondary endpoint. [a]Proportion of patients with 6-month CDI, [b]Cox regression model. CDI, confirmed disability improvement; K-M, Kaplan–Meier

Cemcat

Hauser SL et al. N Engl J Med. 2020;383:546-557.

Ofatumumab: evidence from clinical trials

Effect on number of Gd+ lesions per scan



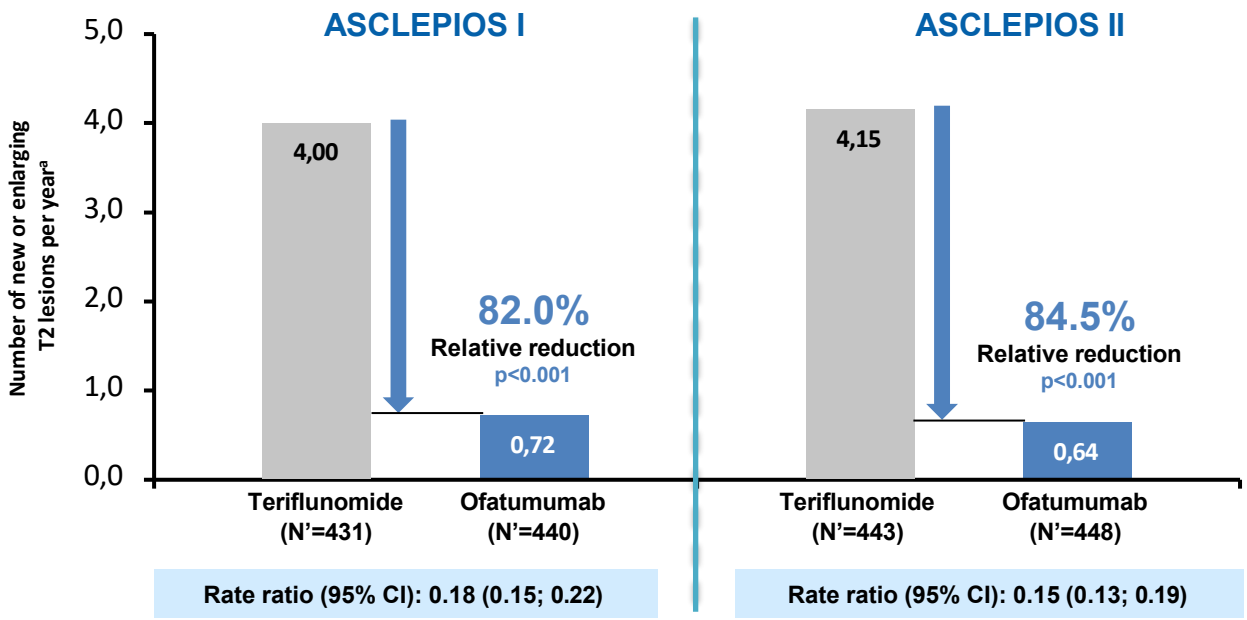
Full analysis set. Secondary endpoint. End of study. [a]Negative binomial regression model of the cumulative number of Gd+ lesions on the M12 and M24 scan, with an offset for the number of available scans. CI, confidence interval; Gd+, gadolinium-enhancing; N', total number of patients included in the analysis

Cemcat

Hauser SL et al. N Engl J Med. 2020;383:546-557.

Ofatumumab: evidence from clinical trials

Effect on number of new or enlarging T2 lesions per year



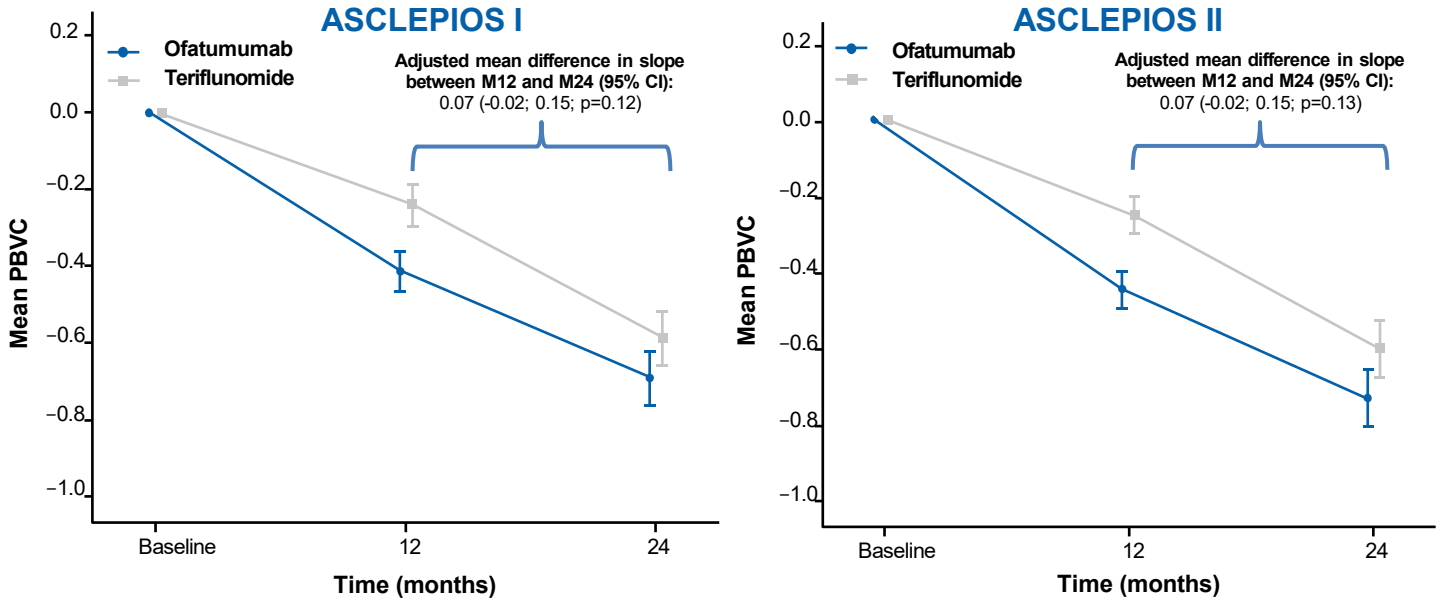
Full analysis set. Secondary endpoint. End of study. [a]Negative binomial regression model of the number of new or enlarging T2 lesions on the last scan relative to the screening scan, with an offset for the time in years between these two scans. CI, confidence interval; N', total number of patients included in the analysis.

Cemcat

Hauser SL et al. N Engl J Med. 2020;383:546-557.

Ofatumumab: evidence from clinical trials

Brain volume change from baseline



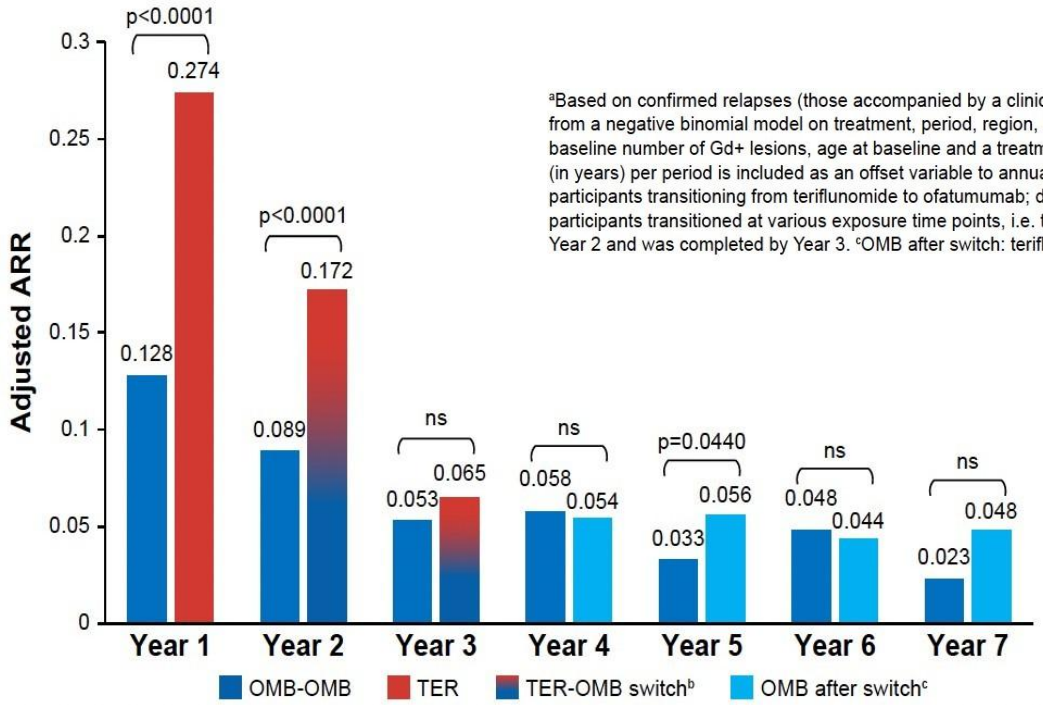
Whole brain volume was analyzed using the Jacobian integration model. Full analysis set. Secondary endpoint. Random coefficient model. CI, confidence interval; M, month; PBVC, percent brain volume change

Cemcat

Hauser SL et al. N Engl J Med. 2020;383:546-557.

Ofatumumab: long-term effectiveness

Figure 2. ARR[a] over 7 years



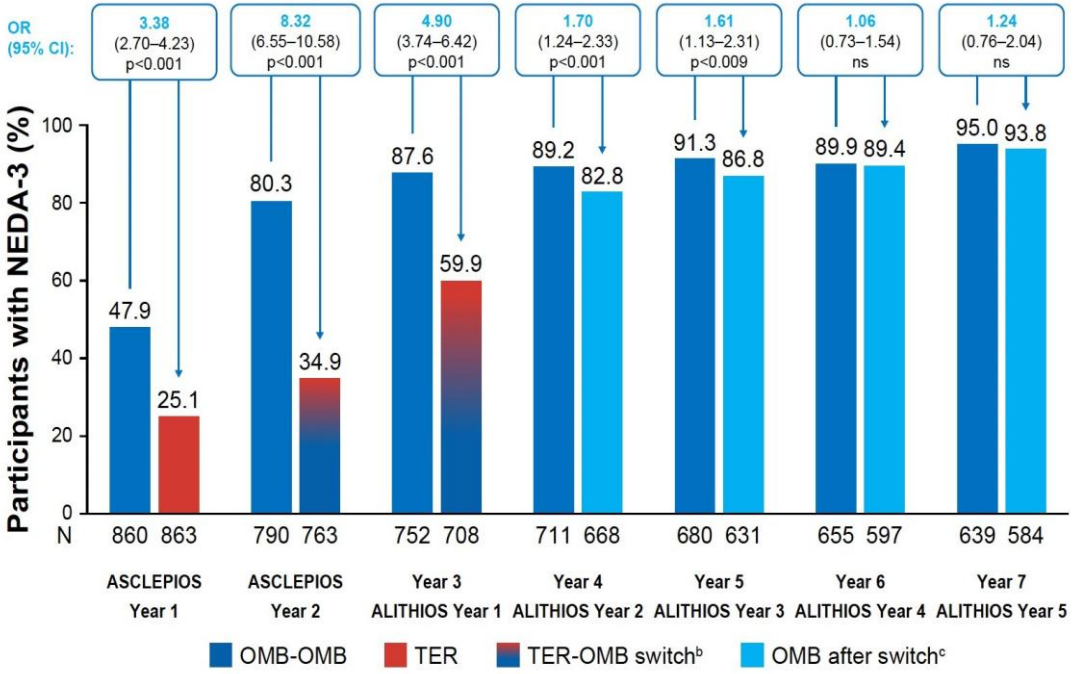
[a]Based on confirmed relapses (those accompanied by a clinically relevant change in the EDSS). ARR are obtained from a negative binomial model on treatment, period, region, number of relapses in previous year, baseline EDSS, baseline number of Gd+ lesions, age at baseline and a treatment by period interaction. Log-transformed exposure time (in years) per period is included as an offset variable to annualise the relapse rate in each period.[b]TER-OMB switch: participants transitioning from teriflunomide to ofatumumab; due to event-driven core study design (flexible duration), participants transitioned at various exposure time points, i.e. the switch from teriflunomide to ofatumumab started from Year 2 and was completed by Year 3. [c]OMB after switch: teriflunomide participants now on ofatumumab.

Cemcat

1. Hauser S, et al. P804. Poster presented at: 41st congress of the ECTRIMS, Barcelona 2025

Ofatumumab: long-term effectiveness

Figure 3. NEDA-3[a] status over 7 years



MRI lesion activity

- An almost complete suppression of Gd+T1 lesion activity (95.6% reduction for ofatumumab vs. teriflunomide in ASCLEPIOS I/II) was maintained from Years 1 to 7 in the OMB-OMB group and from Years 3 to 7 in the TER-OMB group
- An almost-complete suppression of neT2 lesions by Year 2 in the OMB-OMB group was also seen in the TER-OMB group by Year 4 and was maintained in both groups through Year 7

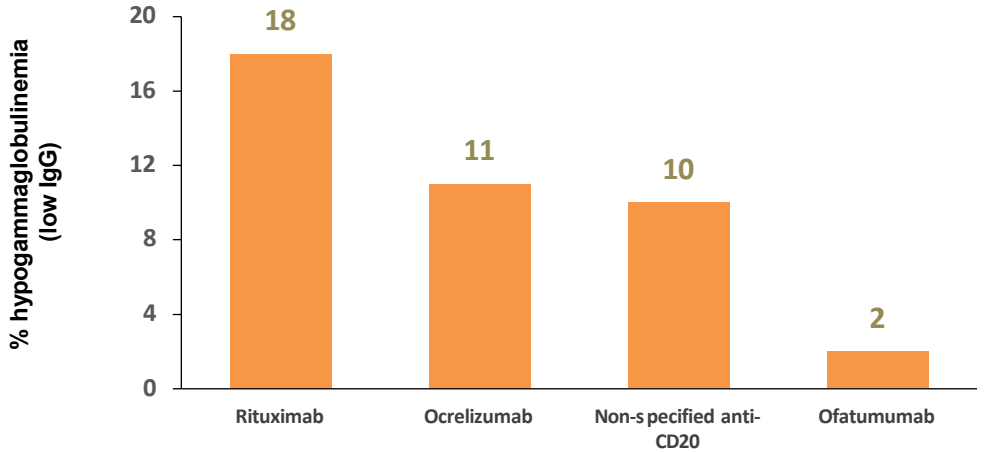
1. Hauser S, et al. P804. Poster presented at: 41st congress of the ECTRIMS, Barcelona 2025

Ofatumumab: long-term safety

Meta-analysis of 19,139 people with MS treated with anti-CD20s[1]

- Overall **prevalence rate** of hypogammaglobulinemia (decreased serum IgG levels): 11% (95% CI: 0.08–0.15)[1]
- Despite the lack of evidence-based guidelines for managing hypogammaglobulinemia and infection risk in patients with MS treated with anti-CD20 therapies, there is consensus for recommending regular monitoring of immunoglobulin levels and monitoring carefully for infections[2]

Prevalence rate of decreased serum IgG levels with anti-CD20 therapies[1]



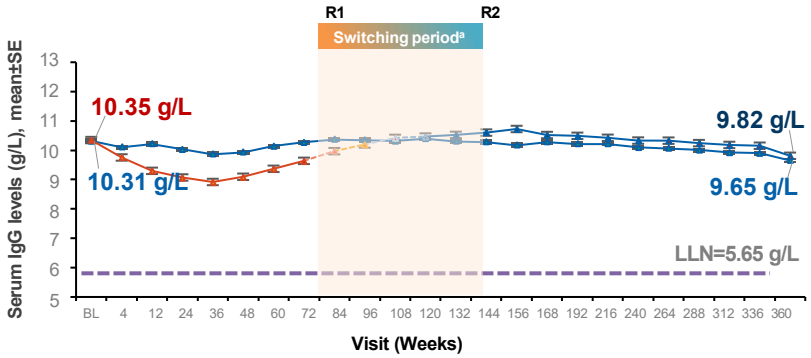
CD, cluster of differentiation; CI, confidence interval; Ig, immunoglobulin.

1. Elgenidy A, *et al*. Front. Neurol. 2024; 15:1380654. 2. Alvarez E, *et al*. Mult Scler Relat Disord. 2023 Nov;79:105009.

Ofatumumab: long-term safety

Mean IgG levels remained stable for up to 7 years of ofatumumab treatment
Mean IgM levels decreased but remained above the LLN

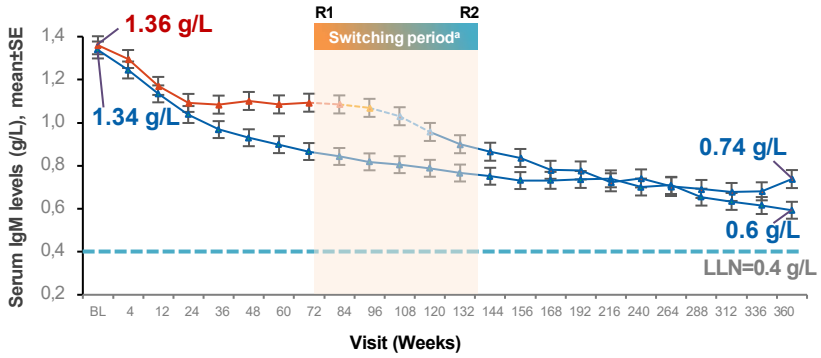
Mean IgG levels[1,2]



Number of patients at visit (n)

	BL	4	12	24	36	48	60	72	84	96	108	120	132	144	156	168	192	216	240	264	288	312	336	360
Continuous OMB	126	123	124	121	117	112	108	903	982	782	908	662	715	525	534	524	819	799	776	754	573	536	424	177
TER-OMB	675	672	673	666	672	669	666	670	635	633	631	564	495	442	350	454	562	542	539	518	523	507	404	151
Pre-switch	675	672	673	666	672	669	666	664/06	477/158	313/320	167/464	72/492												
Post-switch													495	442	350	454	562	542	539	518	523	507	404	151

Mean IgM levels[1,2]



Number of patients at visit (n)

	BL	4	12	24	36	48	60	72	84	96	108	120	132	144	156	168	192	216	240	264	288	312	336	360
Continuous OMB	127	123	125	122	118	113	108	906	986	789	911	669	719	534	542	535	821	803	777	756	574	537	423	177
TER-OMB	675	672	673	666	672	669	666	670	635	633	632	564	502	445	359	456	563	541	539	519	523	507	403	150
Pre-switch	675	672	673	666	672	669	666	664/06	477/158	313/320	167/465	72/492												
Post-switch													502	445	359	456	563	541	539	519	523	507	403	150

The **majority** of participants had **Ig levels above the LLN**: **96.8% for IgG and 64.5% for IgM**

Treatment **interruption** **was** reported in **0.2%** participants due to low **IgG levels** and in **10.4%** participants due to **low IgM levels**

[a]Switching period refers to the participants started on teriflunomide and not applicable to the participants on ofatumumab in the core period. For the teriflunomide/ofatumumab group, data from the first dose of teriflunomide until the last dose of ofatumumab plus 100 days or analysis cutoff date has been used. R1: The first participant with first treatment-emergent assessment in ofatumumab period after switching to ofatumumab (72 weeks); R2: The last participant with last treatment-emergent assessment in teriflunomide period before switching to ofatumumab (120 weeks). For all pooled analyses, a fixed value of LLN (using ALITHIOS study reference) was used: IgG: 5.65 g/L and IgM: 0.4 g/L. BL, baseline; Ig, immunoglobulin; LLN, lower limit of normal; OMB, ofatumumab; SE, standard error of the mean; TER, teriflunomide. 1. Hauser S, et al. P804. Poster presented at: 41st congress of the European Committee for Treatment and Research in Multiple Sclerosis, Barcelona, Spain, 24–26 September 2025. 2. Wiendl H. et al. P9.010. Poster presented at: the American Academy of Neurology Annual Meeting, Denver, CO, USA; 13–18 April 2024.

Ofatumumab: long-term safety

Immunoglobulin G Levels in Ofatumumab-Treated Participants With Episodes of Low Immunoglobulin M: An Analysis of 7-Year Data From the ALITHIOS Extension Study

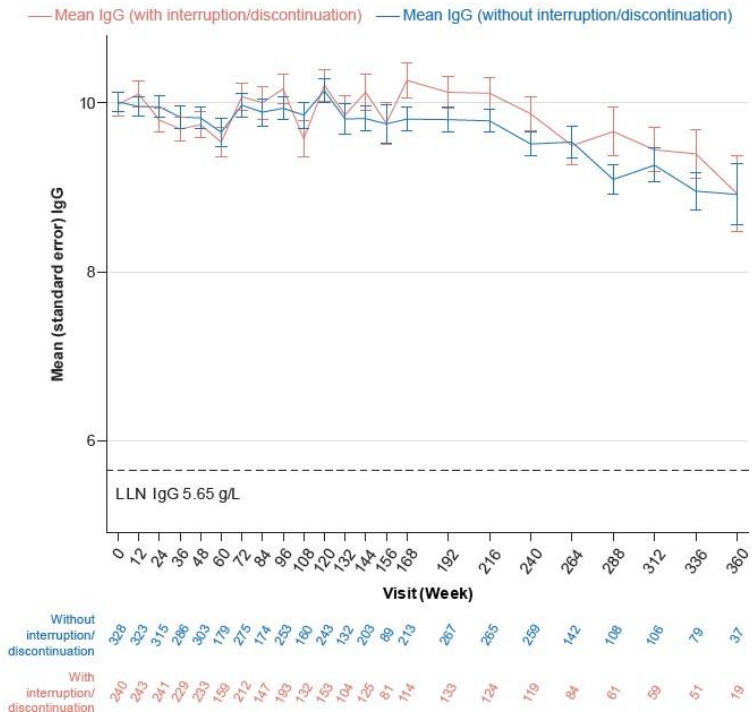
Heinz Wiendl[1], Amit Bar-Or[2], Kevin Winthrop[3], Min Wu[4], Maria Solonets[5], Brandon Brown[4], Anil Abeyewickreme[6], Jun Li[5], Paul Giacomini[7], Masahiro Mori[8], Wallace Brownlee[9]

- The core study protocols mandated drug interruption when IgM or IgG levels dropped 10% or 20% below the LLN, respectively[8]
- This requirement was removed by a protocol amendment (3 June 2021) for ALITHIOS, and the decision was left to the investigator's discretion[8]

Association between serum IgG levels and IgM levels below 10% of the LLN with and without treatment interruptions/discontinuations

- Overall, mean IgG levels were similar and overlapping at all assessments from baseline for up to 7 years in participants with IgM 10% below the LLN with and without interruption/discontinuation, with IgG remaining at least 1.5-fold above the LLN (**Figure 1**)
- Mean IgG (standard error) across all assessments was 9.98 (0.143) versus 10.01 (0.119) g/L, for those with IgM 10% below the LLN with versus without interruption/discontinuation
- The mean duration of follow-up after the first drop of IgM below 10% of the LLN was approximately 2.7 years

Figure 1. Serum IgG levels up to 7 years in participants who experienced notably low IgM (10% below the LLN) with versus without treatment interruption/discontinuation[a]



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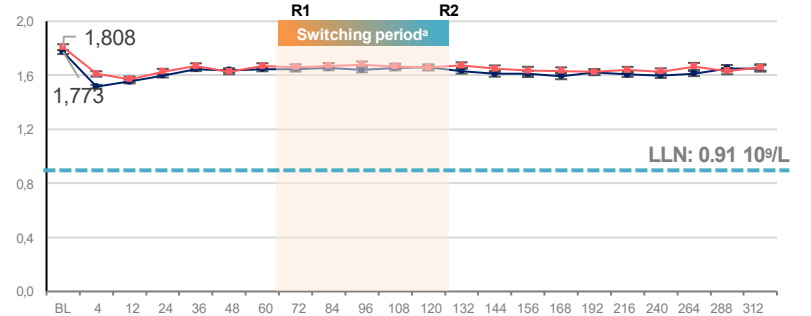
Wiendl et al, Poster session, P932 ECTRIMS 2025

Ofatumumab: long-term safety

Lymphocyte and neutrophil levels remained stable throughout 7 years of ofatumumab treatment[1]

Lymphocyte levels over 6 years[2]

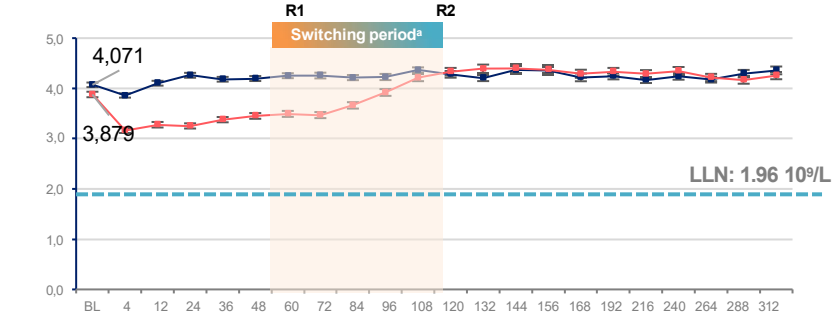


Number of patients at visit (n)

Continuous OMB	1292	1266	1264	1238	1194	1141	1086	901	983	776	918	639	711	492	524	494	804	787	742	717	535	495
TER-OMB	677	670	674	668	670	665	670	671	631	631	634	554	475	424	329	437	547	528	508	482	498	466
Pre-switch	677	670	674	668	670	665	670	665/ 06	480/ 151	313/ 318	170/ 464	72/ 482	475	424	329	437	547	528	508	482	498	466
Post-switch																						

- Mean **lymphocyte levels** remained **close to baseline levels** in continuous and newly switched groups through Week 360 (**up to 7 years**)[1]

Neutrophil levels over 6 years[2]



Number of patients at visit (n)

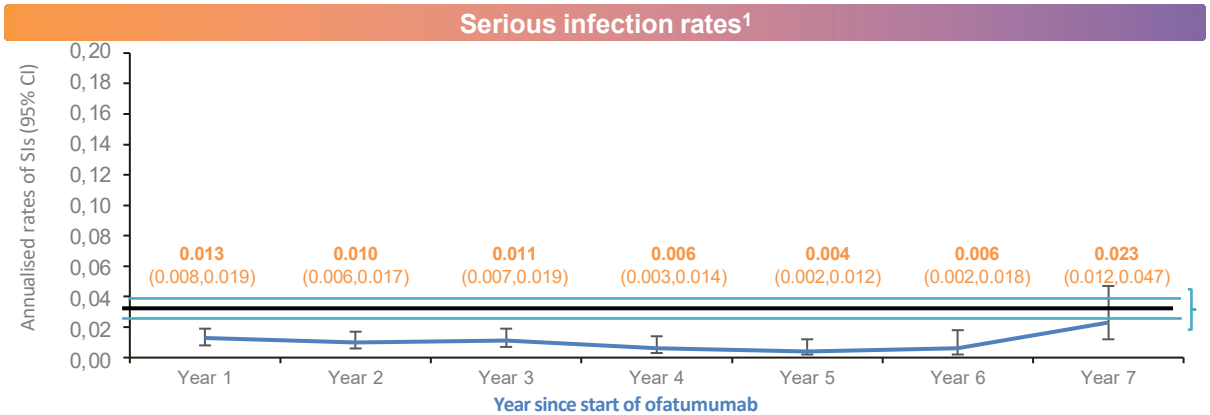
Continuous OMB	1292	1266	1264	1238	1195	1142	1087	901	983	776	918	639	711	492	524	494	804	787	742	717	535	495
TER-OMB	677	670	674	668	670	667	670	671	631	631	634	554	475	424	329	437	547	528	508	482	498	466
Pre-switch	677	670	674	668	670	667	670	665/ 06	480/ 151	313/ 318	170/ 464	72/ 482	475	424	329	437	547	528	508	482	498	466
Post-switch																						

- Mean **neutrophil levels** remained **stable and above baseline** for all visits up to Week 360 (**up to 7 years**)[1]

[a]Switching period refers to the participants started on TER and not applicable to the participants on OMB in the core phase. For the TER/OMB group, data from the first dose of TER until the last dose of OMB plus 100 days or analysis cutoff date has been used. R1: The first participant with first treatment-emergent assessment in OMB period after switching to OMB (72 weeks); R2: The last participant with last treatment-emergent assessment in TER period before switching to OMB (120 weeks). For all pooled analyses, a fixed value of LLN (using ALITHIOS study reference) was used: lymphocytes: 0.91 109/L and neutrophils: 1.96 109/L. BL, baseline; LLN, lower limit of normal; OMB, ofatumumab; SE, standard error of the mean; TER, teriflunomide. 1. Hauser S, et al. P804. Poster presented at: 41st congress of the European Committee for Treatment and Research in Multiple Sclerosis, Barcelona, Spain, 24–26 September 2025. 2. Wiendl H. et al. P9.010. Poster presented at: the American Academy of Neurology Annual Meeting, Denver, CO, USA; 13–18 April 2024.

Ofatumumab: long-term safety

Annualised rate of serious infections (excluding COVID-19) was low and stable throughout 7 years of ofatumumab treatment



German claims database PlwMS, Annualised IR: 0.034 (95% CI 0.030–0.040)[a,2]

Year	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Participants at risk (N)	1969	1812	1619	1500	1408	1217	561
Exposure (PYs)	1904.1	1722.8	1550.8	1455.5	1351.9	783.8	489.4
Number of SI events[b]	25	17	17	9	6	5	11
Participants with at least 1 event, n (%)	23 (1.17)	15 (0.83)	15 (0.93)	5 (0.33)	2 (0.14)	3 (0.25)	8 (1.43)

[a]Cumulative rates of SIs over a median period of 3.9 years (2016–2019) in a German claims database.[2] For comparability, the rates were calculated in a subpopulation of patients with RMS up to the age of 64 years. [b]Possibility of multiple events per participant in a given year. CI, confidence interval; IR, incidence rate; N, number of participants; plwMS, people living with multiple sclerosis; PY, patient-year; SI, serious infection. 1. Ziemssen T, et al. P812. Poster presented at: 41st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), Barcelona, Spain, 24–26 September 2025. 2. Knapp R, et al. Mult Scler Relat Disord 2022;68:104245.

Ofatumumab: long-term safety

A consistent safety profile and low rates of serious infections were observed up to 6 years in early non-highly active MS

- Post hoc analyses from ASCLEPIOS/ALITHIOS include cumulative data up to six years from the early MS subgroup with non-highly active disease activity
- Non-highly active disease activity was defined as:
  - Max. one relapse in the last year and max. two relapses in the last 2 years
  - EDSS ≤3
  - Treatment-naive OR ≤5 years since treatment onset and pre-treated with one prior DMT

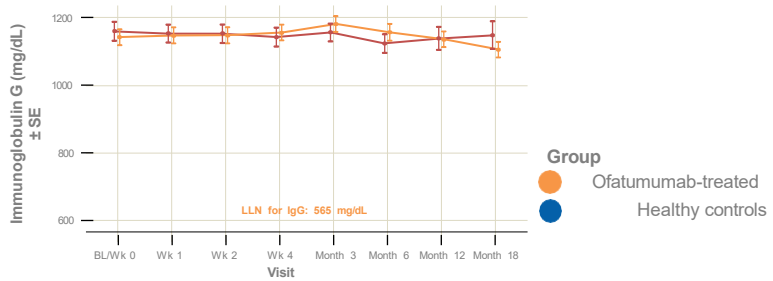
	Core		Core + OLE:
	OMB, n (%) {EAIR [95% CI]} (N=214)	TER, n (%) {EAIR [95% CI]} (N=216)	Overall OMB, n (%) {EAIR [95% CI]} (N=523)
Participants with at least one AE	183 (85.5) {14.2 [12.3-16.4]}	178 (82.4) {14.1 [12.2-16.3]}	365 (93.4) {127.4 [114.9-141.1]}
Participants with at least one SAE	11 (5.1) {0.66 [0.36-1.18]}	12 (5.6) {0.73 [0.42-1.29]}	60 (15.3) {3.53 [2.7-4.6]}
AEs leading to treatment discontinuation	7 (3.3%)	5 (2.3%)	27[a] (6.9)
Infections and infestations	121 (56.5) {8.6 [7.2-10.2]}	118 (54.6) {8.5 [7.1-10.2]}	291 (74.4) {40.6 [36.2-45.6]}
Serious infections	3 (1.4) {0.2 [0.1-0.6]}	1 (0.5) {0.1 [0.0-0.4]}	17 (4.4) {0.94 [0.6-1.5]}
Serious infections (excl. COVID-19)	3 (1.4)	1 (0.5)	9 (2.3)
Serious COVID-19 infections	0	0	8 (2.0) {0.4 [0.2-0.9]}
Injection-related systemic reactions	46 (21.5) {3.1 [2.3-4.1]}	33 (15.3) {2.2[1.6-3.1]}	104 (26.6) {7.3 [6.1-8.9]}
Injection-site reactions	28 (13.1) {1.8 [1.3-2.7]}	12 (5.6) {0.8 [0.5-1.4]}	58 (14.8) {3.6 [2.7-4.5]}
Malignancies	1	2	8 (2.0) {0.4 [0.2-0.9]}
Deaths	0	0	1

[a]Most common (affecting >1.0% of patients in either group) AEs leading to treatment discontinuation in the core phase were 'Blood immunoglobulin M decreased' (OMB: n=5 [2.3%] | TER: n=0 [0.0%]) AE, adverse events; CI, confidence interval; EAIR, exposure-adjusted incidence rate; EDSS, Expanded Disability Status Scale; OLE, open-label extension, OMB, ofatumumab; SAE, serious adverse event; TER, teriflunomide. Ziemssen T, et al. P11.003. Poster presented at the Annual Meeting of American Academy of Neurology (AAN), 05–11 April 2025, San Diego, California, USA.

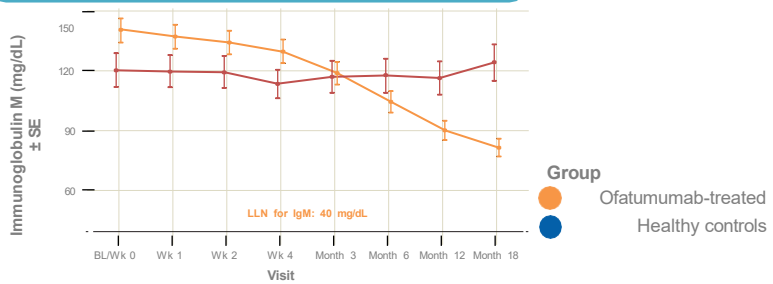
Ofatumumab: long-term safety

AGNOS: The safety profile of ofatumumab in young, treatment-naïve participants with very recently diagnosed RRMS was consistent with prior reports

A. Laboratory parameters over time by visit



B. Laboratory Parameters Over Time by Visit



AGNOS is an 18-month, open-label, multicentre, phase 4 study that included a healthy participant control arm

Treatment-emergent or on-study AEs

All AEs, n (%)	Ofatumumab-treated (n=119)	Healthy control (n=61)
Participants with ≥1 AE	99 (83.2)	28 (45.9)
Treatment-related	81 (68.1)	N/A
AEs leading to study discontinuation	0	0
Most common AEs		
Headache	33 (27.7)	2 (3.3)
Myalgia	31 (26.1)	0
Fatigue	24 (20.2)	1 (1.6)
COVID-19	19 (16.0)	8 (13.1)
Serious AEs	8 (6.7)	3 (4.9)
Treatment-related	3 (2.5)	N/A
Deaths	0	0

AE, adverse event; BL, baseline, Ig, immunoglobulin, LLN, lower limit of normal; N/A, not applicable; RRMS, relapsing-remitting multiple sclerosis; SE, standard error; Wk, week. Hendin B, et al. P428. ECTRIMS 2025 Late Breaking Poster.

Ofatumumab: long-term safety

Anti-CD20 therapies and the risk of malignancy

There are no official recommendations for increased malignancy surveillance screening in PlwMS receiving anti-CD20 therapies[1]

Data from available literature suggests that the associated risk of malignancies appears to be low across anti-CD20 therapies

No evidence of an increased risk of malignancy was observed in RA trials of ocrelizumab; additionally, rituximab and ofatumumab have not been associated with any increased risk of malignancy[1-3]

Although an increased number of malignancies (including breast cancers) was observed in the double-blind period of ocrelizumab MS clinical trials, **the incidence of malignancies remained within the background rate expected for an MS population**[1-4]

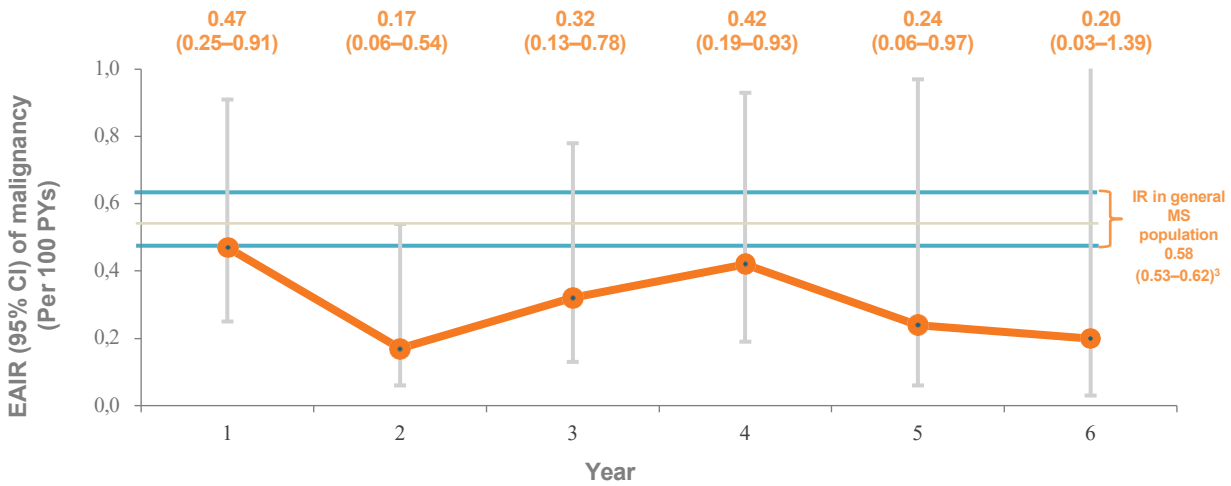
CD, cluster of differentiation; MS, multiple sclerosis; plwMS, people living with multiple sclerosis; RA, rheumatoid arthritis.

1. Greenfield AL, Hauser SL. Ann Neurol. 2018;83:13–26. 2. Delgado SR et al. J Neurol. 2024;271:1515–1535. 4. Emery P, et al. Rheumatol Ther. 2019;7:121–131; 3. Ocrevus SmPC. https://www.ema.europa.eu/en/documents/product-information/ocrevus-epar-product-information_en.pdf. Accessed 22 September 2025.

Ofatumumab: long-term safety

Incidence of malignancies did not increase over time with up to 7 years of ofatumumab treatment[1]

EAIR of malignancy by year (up to Year 6) in the overall safety population[2]



Up to 6 years (core+extension), malignancies were reported in 26 participants (1.3%; EAIR [95% CI]: 0.32 [0.22–0.48])[2]

Up to 7 years (core+extension), malignancies were reported in 29 participants (1.5%; EAIR [95% CI]: 0.31 [0.22–0.45])[1]

CI, confidence interval; EAIR per 100 PYs, exposure-adjusted incidence rate per 100 patient-years; OMB, ofatumumab.

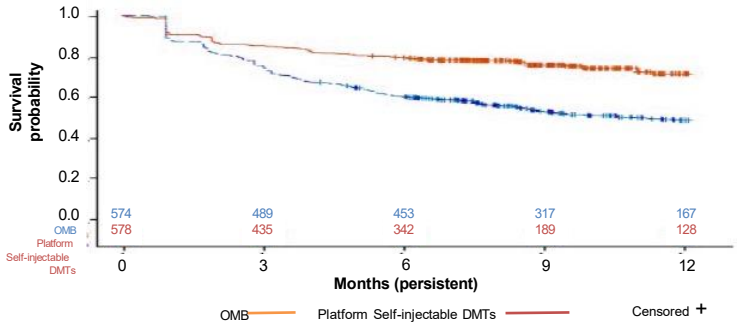
1. Hauser S, et al. P804. Poster presented at: 41st congress of the European Committee for Treatment and Research in Multiple Sclerosis, Barcelona, Spain, 24–26 September 2025. 2. Wiendl H, et al. P9.010. Poster presented at the American Academy of Neurology Annual Meeting, Denver, CO, USA; 13–18 April 2024. 3. Nørgaard M, et al. Mult Scler Relat Disord. 2019;28:81–85.

Ofatumumab: persistence and adherence

Real-world studies[a] have shown that persistence[b] was significantly higher with ofatumumab than with platform self-injectable and oral DMTs

Time to treatment discontinuation

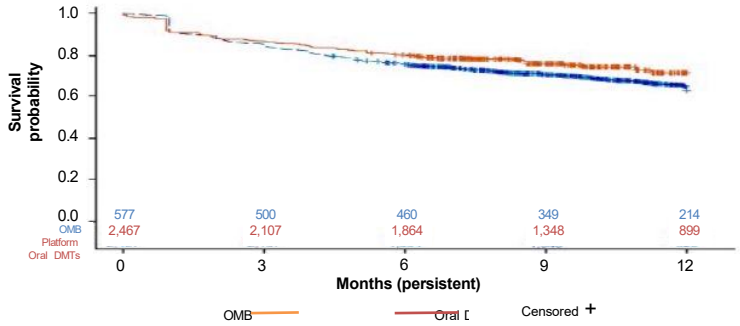
OMB versus platform self-injectable DMTs[c,d]



Log-rank test for OMB vs. Platform Self-injectable DMTs – 60-day gap

Variable	Statistic	StdErr	ChiSq	*p*-value
Cohort	-60.575	7.9676	57.8009	< 0.0001

OMB versus oral DMTs[c,d]



Log-rank test for OMB vs. Oral DMTs – 60-day gap

Variable	Statistic	StdErr	ChiSq	*p*-value
Cohort	-27.2673	8.8397	9.515	0.002

The probability of remaining on treatment over 12 months post-index was higher with ofatumumab than with other self-injectables or oral DMTs

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[a]Retrospective analyses utilisng the IQVIA PharMetrics® Plus data; [b]Persistence was defined as the number of days from the index date until discontinuation of the index therapy or a switch to new DMT; cDiscontinuation is defined as gap in the supply of the index medication, i.e. a gap between the last supply date based on expected duration of treatment or days' supply and the next claim date for the index therapy; dDiscontinuation defined as >60-day gap. DMT, disease-modifying therapy; OMB, ofatumumab. Hersh CM et al. Mult Scler Relat Disord. 2024;91:105888.

Ofatumumab: persistence and adherence

A Real-World Study of Persistence to Ofatumumab in Canada: the CAPES study

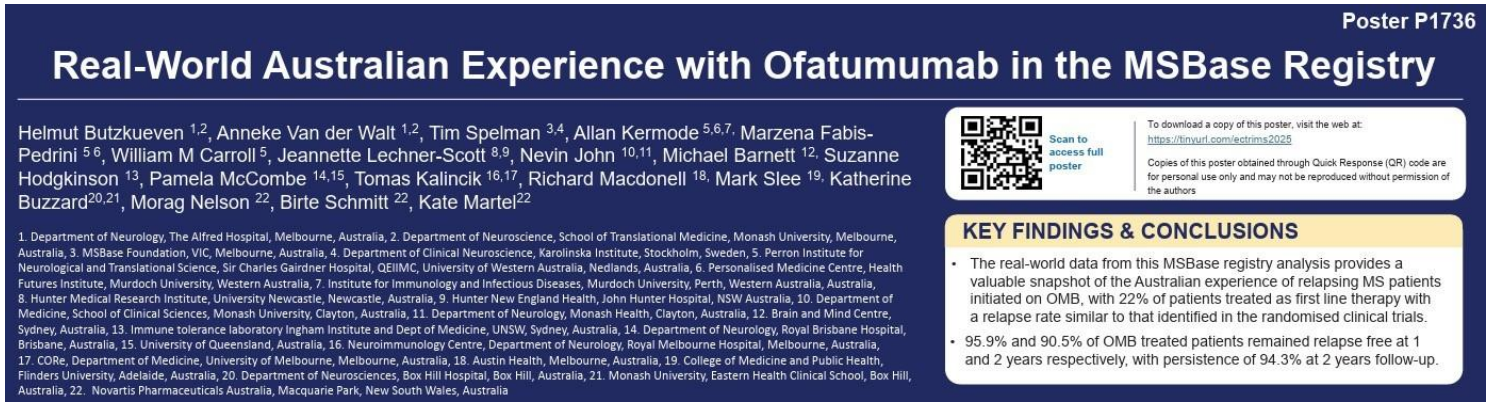
Rebecca Grant[1], Claire Magnussen[1], Jillian Murray[2], Calum S Neish[2]

[1] Novartis Pharmaceuticals Canada Inc, Montreal, Canada; [2] IQVIA Solutions Canada, Mississauga, Canada

This study is sponsored by Novartis Pharma AG
Poster presented at the 41st ECTRIMS Congress, held in Barcelona, Spain 24–26 Sept 2025

KEY FINDINGS & CONCLUSIONS

- High persistence to ofatumumab was found over three years.
- Persistence probability was 96.9% at one-year, 95.0% at two-years, and 92.3% at three-years.
- Discontinuation was low (3.1%); most common reasons were side effects (0.9%) and trying to conceive/pregnancy (0.5%)
- Such high real-world persistence and low discontinuation with ofatumumab complement data from randomized controlled clinical trials and suggests that self-administered ofatumumab is an efficacious, well-tolerated, and convenient option for patients.



Poster P1736

Real-World Australian Experience with Ofatumumab in the MSBase Registry

Helmut Butzkueven [1,2], Anneke Van der Walt [1,2], Tim Spelman [3,4], Allan Kermode [5,6,7], Marzena Fabis-Pedrini [5,6], William M Carroll [5], Jeannette Lechner-Scott [8,9], Nevin John [10,11], Michael Barnett [12], Suzanne Hodgkinson [13], Pamela McCombe [14,15], Tomas Kalincik [16,17], Richard Macdonell [18], Mark Slee [19], Katherine Buzzard[20,21], Morag Nelson [22], Birte Schmitt [22], Kate Martel[22]

1. Department of Neurology, The Alfred Hospital, Melbourne, Australia, 2. Department of Neuroscience, School of Translational Medicine, Monash University, Melbourne, Australia, 3. MSBase Foundation, VIC, Melbourne, Australia, 4. Department of Clinical Neuroscience, Karolinska Institute, Stockholm, Sweden, 5. Perron Institute for Neurological and Translational Science, Sir Charles Gairdner Hospital, QEIIMC, University of Western Australia, Nedlands, Australia, 6. Personalised Medicine Centre, Health Futures Institute, Murdoch University, Western Australia, 7. Institute for Immunology and Infectious Diseases, Murdoch University, Perth, Western Australia, Australia, 8. Hunter Medical Research Institute, University Newcastle, Newcastle, Australia, 9. Hunter New England Health, John Hunter Hospital, NSW Australia, 10. Department of Medicine, School of Clinical Sciences, Monash University, Clayton, Australia, 11. Department of Neurology, Monash Health, Clayton, Australia, 12. Brain and Mind Centre, Sydney, Australia, 13. Immune tolerance laboratory Ingham Institute and Dept of Medicine, UNSW, Sydney, Australia, 14. Department of Neurology, Royal Brisbane Hospital, Brisbane, Australia, 15. University of Queensland, Australia, 16. Neuroimmunology Centre, Department of Neurology, Royal Melbourne Hospital, Melbourne, Australia, 17. CORe, Department of Medicine, University of Melbourne, Melbourne, Australia, 18. Austin Health, Melbourne, Australia, 19. College of Medicine and Public Health, Flinders University, Adelaide, Australia, 20. Department of Neurosciences, Box Hill Hospital, Box Hill, Australia, 21. Monash University, Eastern Health Clinical School, Box Hill, Australia, 22. Novartis Pharmaceuticals Australia, Macquarie Park, New South Wales, Australia

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KEY FINDINGS & CONCLUSIONS

- The real-world data from this MSBase registry analysis provides a valuable snapshot of the Australian experience of relapsing MS patients initiated on OMB, with 22% of patients treated as first line therapy with a relapse rate similar to that identified in the randomised clinical trials.
- 95.9% and 90.5% of OMB treated patients remained relapse free at 1 and 2 years respectively, with persistence of 94.3% at 2 years follow-up.

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Ofatumumab: persistence and adherence

A Cross-Sectional Study to Assess the Effectiveness and Safety of Ofatumumab in Patients with Relapsing Multiple Sclerosis in Clinical Practice: the CRONOS-MS Study

Celia Oreja-Guevara[1]; Irene Gómez Estévez[1]; Rosario Blasco Quílez[2]; Ana María Alonso Torres[3]; Sergio Martínez Yelamos[4]; Francisco Carlos Pérez Miralles[5]; Francisco Gascón Gimenez[6]; Alba Rodríguez Martín[7]; Lucienne Costa-Frossard[8]; Ángel Perez Sempere[9]; Yolanda Blanco Morgado[10]; Andrés Labiano Fontcuberta[11]; Claudia Villar Van Den Weygaert[12]; Vanesa Núñez Gutierrez[13]; Francisco Javier Barrero Hernández[14]; Luis Hernández Echevarría[15]; Berta Sebastián Torres[16]; Julia Gracia Gil[17]; Mª Luisa Martínez Gines[18]; Inmaculada García Castañón[19]; Elena Álvarez Rodríguez[20]; María Eugenia Marzo Sola[21]; Sabas Boyero Duran[22]; Gary Cicerón Álvarez Bravo[23]; Sara Eichau Madueño[24]; Jose Mª Prieto González[25]; María Díaz Sanchez[26]; Montserrat Gómez Gutiérrez[27]; Inmaculada Puertas Muñoz[28]; Maria Otano Martínez[29]; Vicente González Quintanilla[30]; Virginia Delgado Gil[31]; Laura Aguado García[32]; Carolina Isart Ferré[33]; Eduardo Agüera Morales[7]

Table 1. Demographics and baseline clinical characteristics of patients included in the analysis[1]

Characteristics	
Age, mean (SD)	42.2 (9.8)
Female, n (%)	212 (68.4)
Comorbidities (yes), n (%) (N=308)	179 (58.1)
Time from diagnosis (years), mean (SD)	8.4 (8.1)
ARR in the 12 months before ofatumumab (95% CI)	0.66 (0.59-0.75)
EDSS (last score ≤6 months before ofatumumab), mean (SD) (N=295)	2.1 (1.4)
Presence of at least one T1 Gd+ lesion, n (%) (N=222)	79 (35.6)
Number of T1 Gd+ lesions, median (IQR) (N=70)	1.5 (1.0)
Presence of infratentorial lesions, n (%) (N=253)	176 (69.6)
Presence of spinal cord lesions, n (%) (N=215)	150 (69.8)
Patients with prior DMT, n (%) (N=309)	203 (65.7)
Last DMT recorded (N=203)[2]	
Moderate-efficacy DMT, n (%)	113 (55.7)
High-efficacy DMT, n (%)	86 (42.4)

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Ofatumumab: persistence and adherence

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Adherence

- All the initial doses (week 0, 1 and 2) were received by 99% of the patients (N=307) and 98.7% (N=306) patients received all subsequent monthly doses.

Discontinuation

- Only eight (2.6%) patients discontinued treatment. The reasons for discontinuation were lack of efficacy (N=3), AEs (N=1), route of administration (N=1), patient preference (N=1) and other reasons (N=2).

Table 2: Adverse events in patients treated with ofatumumab

Adverse event (AE)	n (%)
Patients with any AE	197 (63.6)
Type of AE[1]	
Upper respiratory tract infections	46 (14.8)
Urinary tract infections	14 (4.5)
Oral herpes	8 (2.6)
Local reaction at the injection site	18 (5.8)
Systemic reaction related to the injection	93 (30.0)
Decrease in blood immunoglobulin M	1 (0.3)
Others	232 (74.8)

[1]Patients with at least one event of each type.

Ofatumumab at Cemcat

C Criteris clínics d'inici i seguiment

PHF | Programa d'Harmonització Farmacoterapèutica

Annex a l'acord de la CFT-SISCAT

Criteris clínics d'inici i seguiment de natalizumab, fingolimod, ozanimod, ponesimod, ocrelizumab, ofatumumab, ublituximab, alemtuzumab i cladribina per al tractament de l'esclerosi múltiple recurrent-remitent amb fàrmacs d'alta eficàcia

L'objectiu del tractament és reduir la freqüència i gravetat de les brotades, així com l'aparició de lesions desmielinitzants noves per a prevenir o retardar l'acumulació de la discapacitat i aconseguir l'absència d'activitat de la malaltia.

Ofatumumab at Cemcat

[4] Es considera malaltia activa quan el pacient presenta una de les situacions següents: 1 brotada en el darrer any o un augment significatiu de la càrrega lesional (aparició de ≥ 2 lesions noves en T2) respecte a l'última RM cranial o ≥ 1 lesió captant de gadolini a l'última RM cranial.

Inici del tractament

Es consideren candidats a rebre tractament amb natalizumab, fingolimod, ozanimod, ponesimod, ocrelizumab, ofatumumab, alemtuzumab[1], cladribina i ublituximab aquells pacients que compleixen els criteris següents:

- Diagnòstic definit d'esclerosi múltiple remitent-recurrent (EMRR)[2] segons criteris McDonald 2017[3] i
- Malaltia activa[4] amb criteris de mal pronòstic.

Es consideren criteris de mal pronòstic si el pacient presenta almenys una de les situacions següents, independentment de si ha rebut o no tractament previ:

- presència de lesions en medul·la o en fossa posterior a l'última RM cranial.
- noves lesions captants de gadolini o lesions T2 hiperintenses en RM recent (≤ 12 mesos).
- recuperació incompleta dels brots en els primers 12 mesos.
- interval curt de temps entre la primera i la segona brotada en un període inferior a 1 any.
- empitjorament EDSS (independentment de presència de brot) en un període inferior a 12 mesos:
  - Augment ≥ 1 punt en cas d'EDSS previ < 5,5 o
  - Augment ≥ 0,5 punts en cas d'EDSS previ ≥ 5,5.

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Ofatumumab at Cemcat

Decisions Compartides

Generalitat de Catalunya
Departament de Salut

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Ofatumumab at Cemcat

Decisions Compartides

Generalitat de Catalunya
Departament de Salut

Kesimpta Ofatumumab | Muy Alta | Mensual | Efectos

Nombre comercial
Kesimpta
Principio activo
Ofatumumab
Criterios para recibir el tratamiento
EM de alta actividad
Eficacia
Reducción aproximada del 53% en el número de brotes en un año (respecto a teriflunomida);Muy alta;;
Frecuencia
Cada 4 semanas (Dosis iniciales semana 0, 1 y 2);Mensual
Vía de administración
Subcutánea
Lugar de administración
Domicilio
Controles analíticos y visitas
Visita y analítica antes de iniciar el tratamiento. Posteriormente, el 3º y el 6º mes.
Efectos secundarios más frecuentes
Síndrome pseudogripal Reacción en el sitio de inyección Infecciones del tracto respiratorio superior y urinario Posible disminución de la respuesta a vacunas
Embarazo y lactancia
Durante el embarazo debe evitarse a menos que el beneficio potencial para la madre supere el riesgo potencial para el feto. Las mujeres en edad fértil deben utilizar métodos anticonceptivos efectivos durante el tratamiento y durante 6 meses tras la última administración. Riesgo bajo en la lactancia

Cemcat

Opciones para Filtrar

Buscar: Introduzca el texto a buscar

Borrar Filtros | Compara 0

Criterios para recibir el tratamiento

Esclerosis Múltiple Remitente-Recurrente (EMRR):
- EMRR de actividad moderada
- EMRR de alta actividad

Formas progresivas:
- EMRR progresiva

Frecuencia

Periodicidad en la qual quieres recibir el tratamiento:
- Diaria
- Diversas veces a la semana
- Semanal
- Quincenal
- Mensual
- Semestral
- Anual

Eficacia

Capacidad del tractamiento para reducir el número de brotes o la progresión de la malaltía:
- Moderada
- Alta
- Muy Alta

Vía de administración

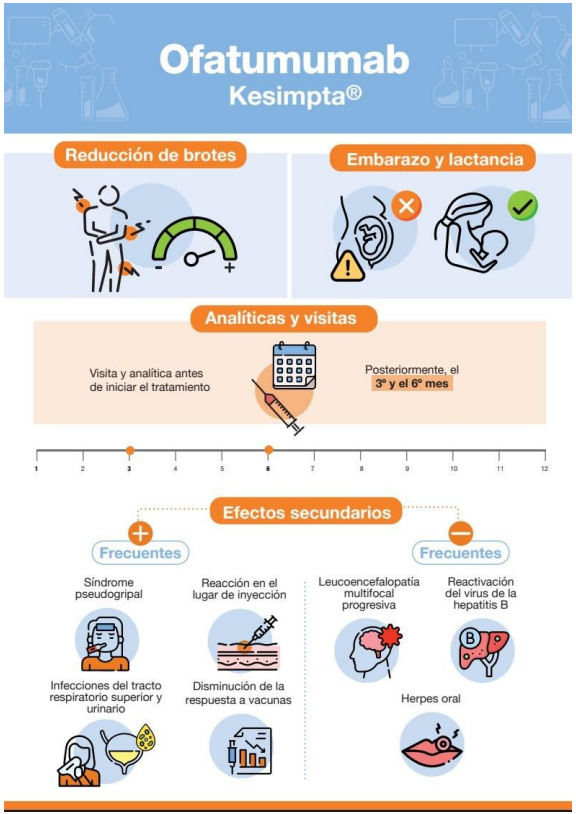
Manera en la que quieres recibir el tratamiento:
- Oral
- Subcutáneo / Intramuscular
- Intravenoso

Nombre comercial / Principio activo	Eficacia	Frecuencia	Vía	Efectos secundarios	Compara
Aubagio / Genérico — Teriflunomida	Moderada	Diaria		Efectos	
Avonex — Interferón beta-1a	Moderada	Semanal		Efectos	
Betaferon / Extavia — Interferón beta-1b	Moderada	Diversas		Efectos	
Copaxone / Genérico — Acetato de glatirámero	Moderada	Diversas		Efectos	
Gilenya / Genérico — Fingolimod	Alta	Diaria		Efectos	
Kesimpta — Ofatumumab	Muy Alta	Mensual		Efectos	
Lemtrada — Alemtuzumab	Muy Alta	Anual		Efectos	
Mavenclad — Cladribina	Alta	Anual		Efectos	
Mayzent — Siponimod	Moderada	Diaria		Efectos	
Ocrevus — Ocrelizumab	Muy Alta	Semestral		Efectos	
Plegridy — Peginterferón beta-1a	Moderada	Quincenal		Efectos	
Ponvory — Ponesimod	Alta	Diaria		Efectos	
Rebif — Interferón beta-1a_1	Moderada	Diversas		Efectos	
Tecfidera / Genérico — Dimetil fumarado	Moderada	Diaria		Efectos	
Tysabri / Tyruko — Natalizumab	Muy Alta	Mensual		Efectos	
Vumerity — Fumarato de diroximel	Moderada	Diaria		Efectos	
Zeposia — Ozanimod	Alta	Diaria		Efectos	

Ofatumumab at Cemcat

Decisions Compartides

Generalitat de Catalunya
Departament de Salut



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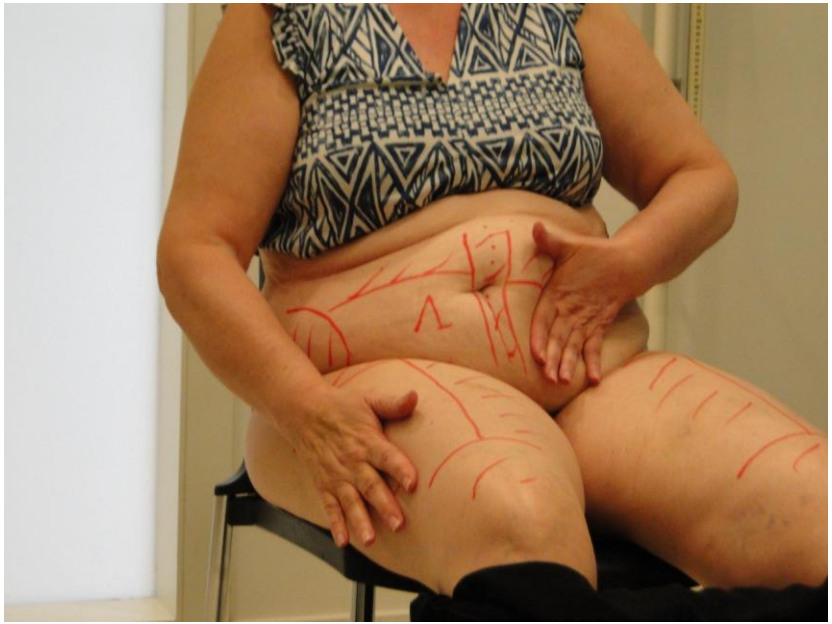
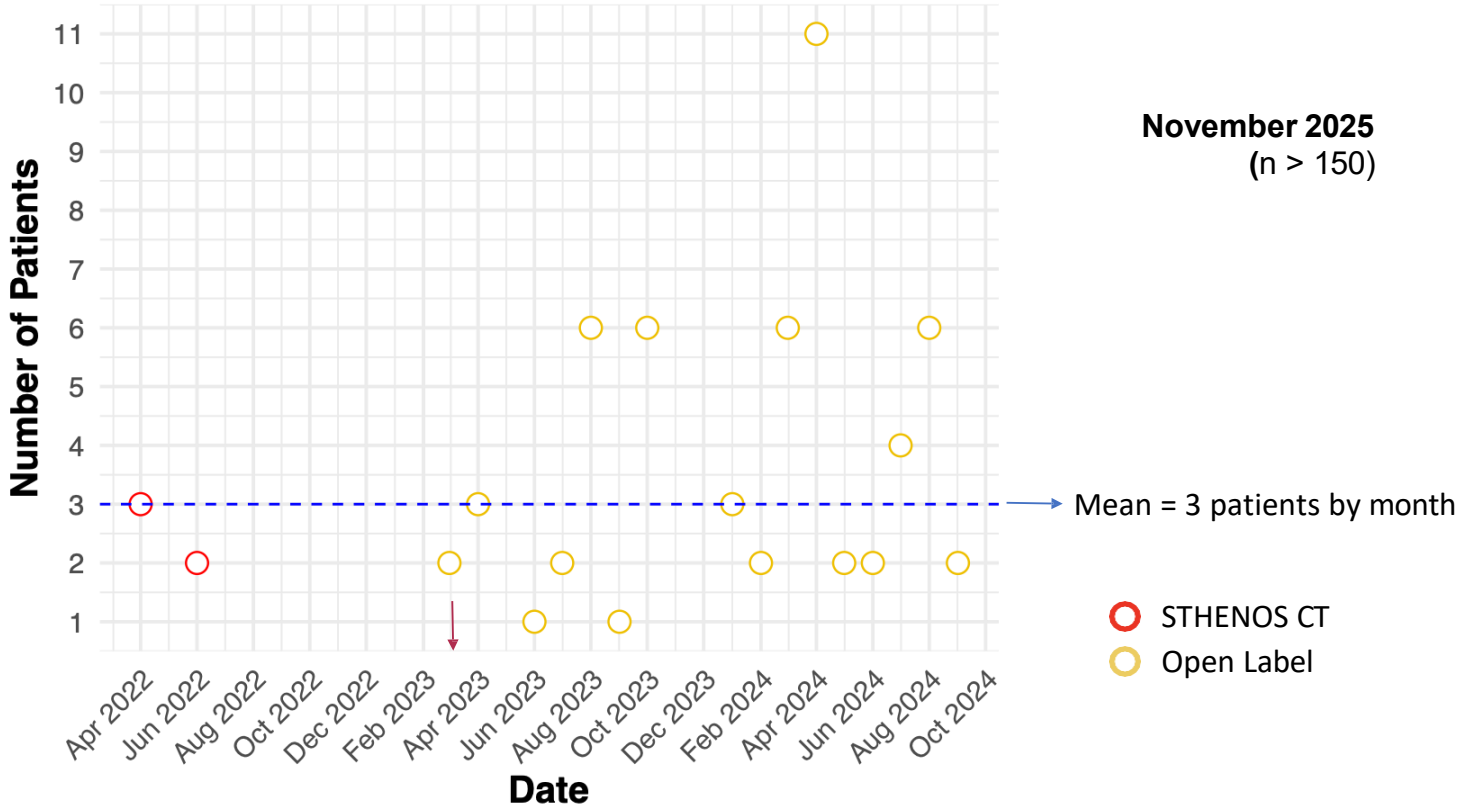
Ofatumumab at Cemcat

Ofatumumab at Cemcat



Ofatumumab at Cemcat

Ofatumumab at Cemcat



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Ofatumumab at Cemcat

Variables	N = 64
Sex, n (%)	
female	37 (58%)
male	27 (42%)
Age in years, mean (SD)	37 (9)
Disease Duration in years, median (IQR)	3.9 (0.5 - 9.2)
Phenotype, n (%)	
relapsing-remitting MS	64 (100%)
EDSS, median (IQR)	1.50 (1.00 - 2.50)
Number of Treatments before OMB, median (IQR)	1 (0 - 2)
Treatment before OMB, n (%)	
Cladribine	3 (4.7%)
Clinical Trial *	1 (1.6%)
Dimethyl fumarate	15 (23%)
Fingolimod	2 (3.1%)
Glatiramer Acetate	3 (4.7%)
Naive	30 (47%)
Natalizumab	2 (3.1%)
Ocrelizumab	3 (4.7%)
Ponesimod	1 (1.6%)
Teriflunomide	4 (6.3%)
1-year AAR before OMB, mean (SD)	1 (1)
Activity in baseline MRI, n (%)	35 (55%)
New T2 lesions, mean (SD)	2.55 (3.68)
(N/A)	22
Contrast-enhancing lesions, mean (SD)	0.59 (0.97)
(N/A)	25

Abbreviations: MS = multiple sclerosis. OMB = Ofatumumab. EDSS = expanded disability status scale. N/A = no available

November 2025
(n > 150)

Disease duration
- 50% ≤ 4y
- 25% ≤ 0.5y

EDSS
- 50% ≤1.5
- 25% ≤1.0

Previous therapy
- ≈50% naïve

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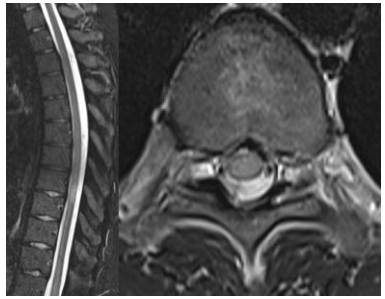
Clinical case

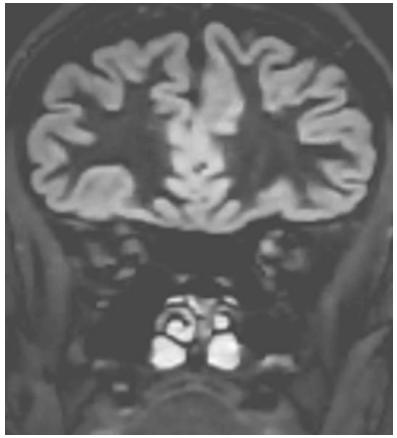
Age: 28
Sex: female

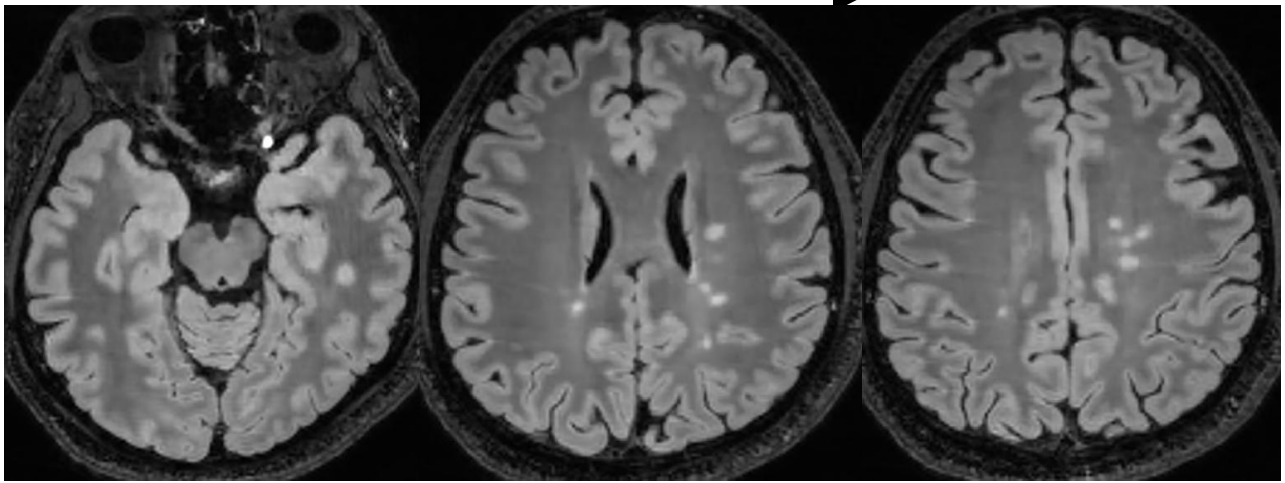


January 2022

2017

CIS (optic neuritis)





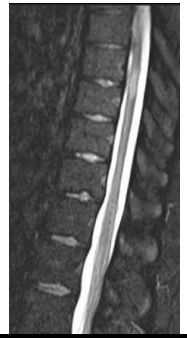
Start treatment with **natalizumab** Jan 2022
vJC positive (high index)

No relapses, no disability progression
MRI: no new lesions

Clinical case

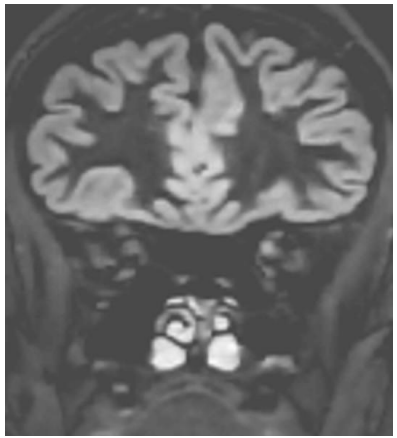
Age: 28
Sex: female

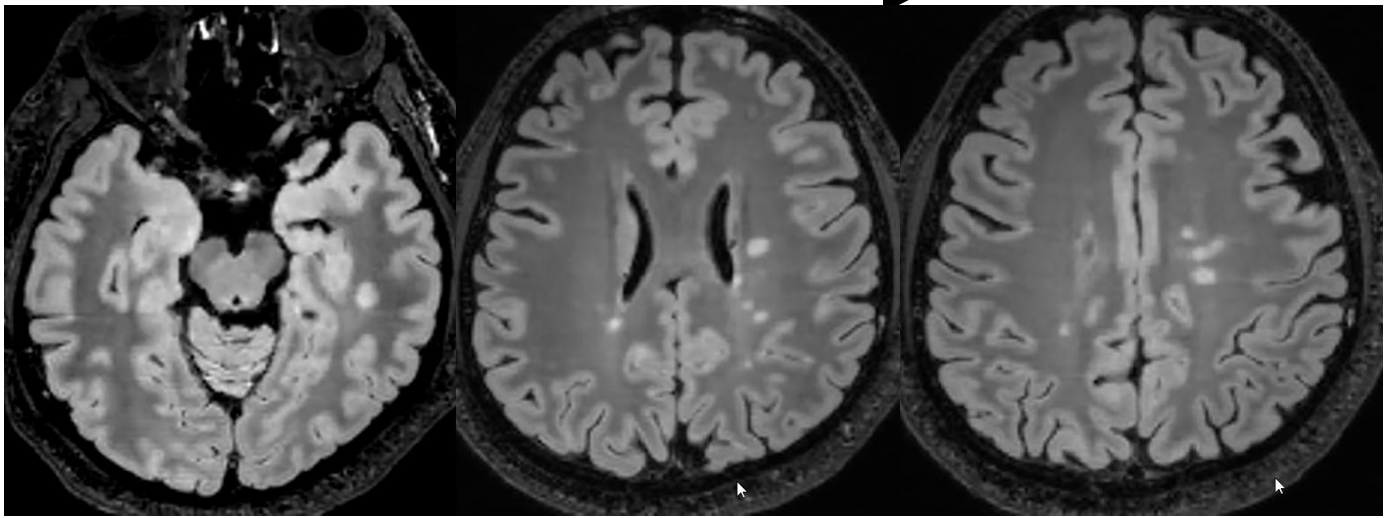
November 2025



2017

CIS (optic neuritis)



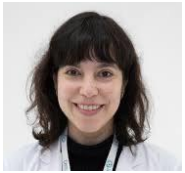


Start treatment with **ofatumumab** April 2023
No relapses, no disability progression
MRI (02/24): no new lesions (brain and spinal cord)
Normal IgG levels

Cemcat
Centre d'Esclerosi Múltiple de Catalunya


Dra. Àngela Vidal-Jordana


Sr. M.A. Robles


Dr. G. Arrambide

Magnims
Magnetic Resonance Imaging in Multiple Sclerosis

Vall d'Hebron Barcelona Hospital Campus

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Ofatumumab en esclerosis múltiple

Jaume Sastre-Garriga @J_SastreGarriga

Servei de Neurologia

Centre d'Esclerosi Múltiple de Catalunya – Cemcat

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¡Muchas gracias!

Novartis Argentina S.A
Ramallo 1851 - C1429DUC Buenos Aires - Argentina
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