

A Multicenter Study of Continued Current Therapy vs Transition to Ofatumumab After Neurofilament (NfL) Elevation

Last Update: Jul 08, 2025

A Randomized, Open Label, Multi-center, Active-comparator Study to Assess Efficacy, Safety & Tolerability of Ofatumumab 20mg sc Monthly Versus Continued Current Therapy in Relapsing-remitting Multiple Sclerosis After Elevation of Serum Neurofilament Light Levels (SOSTOS)

ClinicalTrials.gov Identifier:

[NCT05090371](#)

Novartis Reference Number:COMB157GUS09

[See if you Pre-qualify](#)

All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

This study will evaluate if relapsing-remitting MS patients that have not had a relapse in the past year would benefit from a switch to ofatumumab versus staying on their continued current therapy. This study will also look at whether an elevated serum neurofilament light (NfL) level predicts enhanced benefit from a switch to ofatumumab. This is a multicenter, prospective study of up to 150 relapsing-remitting MS participants/ The study is looking to see if patients who have not had a relapse in the past year would benefit from switching to ofatumumab.

After giving consent, participants will have a 1 week screening/qualification period. If they qualify to continue, they will start a a six month run-in period during which lab samples will be collected. Patients that are relapse-free during the run-in period will continue into next period of the study in which they will be randomized to either ofatumumab or continued therapy for the next 15 months. Every 3 out of 5 randomized participants will be selected to wear a digital study watch to collect physical activity, sleep, and vitals during this 15 month period. The study watch will be worn 24 hours a day, 7 days a week but can be removed during showers/bathing. At the end of the 15 month period, a study completion visit will be held.

The total study duration is 21 months plus 1 week for screening/qualification.

Condition

Relapsing-Remitting Multiple Sclerosis

Phase

Phase4

Overall Status

Recruiting

Number of Participants

150

Start Date

Mar 02, 2022
Completion Date
Dec 31, 2026
Gender
All
Age(s)
18 Years - 50 Years (Adult)

Interventions

Drug

Disease modifying treatment (DMT)

Other DMT with approved label use for treatment which participants were on at least 6 months prior to Screening
Drug

Ofatumumab

3 loading doses followed by administration every 4 weeks as per label

Eligibility Criteria

Inclusion Criteria:

- * Signed informed consent must be obtained prior to participation in the study.
- * Age 18-45 years
- * Diagnosis of RRMS per McDonald Criteria (2017)
- * EDSS 0-5.5 (Inclusive)
- * Able to obtain MRI and attend study visits at sites
- * Willing to use wearable device as specified in the protocol
- * Able to provide blood sample
- * On a current DMT with approved label use for treatment of RRMS at least 6 months prior to Screening
- * No relapse reported within 6 months prior to Screening
- * Patients may enroll in the trial if they have subclinical disease activity as measured by MRI prior to enrollment. An absence of MRI activity is not exclusionary.

Exclusion Criteria:

- * Primary progressive or secondary progressive phenotype
- * Diseases other than multiple sclerosis responsible for the clinical or MRI presentation
- * Use of experimental or investigational drugs for MS within 2 years from Screening
- * Known sensitivity to gadolinium
- * Central Nervous System (CNS) anomalies that are better accounted for by another disease process
- * Known active malignancies
- * Active chronic disease (or stable but treated with immune therapy) of the immune system other than MS
- * Active infections including systemic bacterial, viral (including COVID-19) or fungal infections, known to have AIDS or tested positive for HIV antibodies

* Neurological findings consistent with Progressive Multifocal Leukoencephalopathy (PML), or confirmed PML

* IgG or IgM levels below lower limit of normal (LLN) at Screening

Canada

Novartis Investigative Site

Recruiting

Granby, Quebec, J2g 1t7, Canada

Novartis Investigative Site

Recruiting

Levis, Quebec, G6w 0m5, Canada

Novartis Investigative Site

Recruiting

Saskatoon, Saskatchewan, S7k 0m7, Canada

Novartis Investigative Site

Recruiting

Edmonton, Alberta, T6g 2b7, Canada

Novartis Investigative Site

Recruiting

Vancouver, British Columbia, V6t 2a1, Canada

Novartis Investigative Site

Recruiting

Burnaby, British Columbia, V5g 2x6, Canada

United States

Palmetto Clinical Research

Recruiting

Summerville, South Carolina, 29485, United States

Robert Carlile

Phone: 843-851-7098

Recruiting

Orlando,Florida,32806,United States

Tiffany Gilliard

Phone: 407-352-5434

Email: Tiffany.gilliard@orlandohealth.com

Amparo Gutierrez

Kootenai Health

Recruiting

Coeur d'Alene,Idaho,83815,United States

Phone: 208-625-5273

Nina Bozinov

Covenant Medical Group

Recruiting

Lubbock,Texas,79410,United States

Bhupesh Dihenia

Phone: 806-722-3500

Homestead Assoc In Research Inc

Recruiting

Homestead,Florida,33033,United States

Phone: 305-246-0873

Angel Carrasco

Aurora BayCare Medical Center

Recruiting

Green Bay,Wisconsin,54311,United States

James Napier

Phone: 920-288-8100

Arizona Neuroscience Research LLC

Recruiting

Phoenix,Arizona,85032,United States

Leslie Zuniga

Phone: 480-210-8723

University Of NC At Chapel Hill

Recruiting

Chapel Hill,North Carolina,27599 9500,United States

Phone: 919-945-4752

Irena Dujmovic Basuroski

Reliant Medical Group

Recruiting

Worcester,Massachusetts,01608,United States

Gary Keilson

Candace Leblanc

Phone: 508-368-3168

Email: candace.leblanc@reliantmedicalgroup.org

North Central Neurology Associates PC

Recruiting

Cullman,Alabama,35058,United States

Phone: 256-739-1210

Christopher LaGanke

Neuro Mind Clinical Trials Ltd Co

Recruiting

Katy,Texas,77449,United States

Jontel Pierce

Sibyl Wray MD Neurology PC

Recruiting

Knoxville,Tennessee,37922,United States

Phone: 865-218-6222

Sibyl Wray

Henry Ford Hospital

Recruiting

Detroit,Michigan,48202 2689,United States

Phone: 313-556-8186

Mirela Cerghet

West Texas Cancer Center

Recruiting

Odessa,Texas,79761,United States

Phone: 432-368-2138

Cathy Sabouni

Medical College of Wisconsin

Recruiting

Milwaukee,Wisconsin,53226,United States

Phone: 414-955-0693

Ahmed Obeidat

University of California at Los Angeles

Recruiting

Torrance,California,90509-2004,United States

Phone: 949-547-6875

Bijal Mehta

Jersey Shore University Medical Ctr

Recruiting

Neptune,New Jersey,07753,United States

Phone: 732-776-4782

David Duncan

Evergreen Health Multiple Sclerosis Center

Recruiting

Kirkland, Washington, 98034, United States

Phone: 425-899-5385

Jason Poon

Neuro Medial Clinic of Central Louisiana

Recruiting

Alexandria, Louisiana, 71301, United States

Phone: 318-769-2862

Ariel Antezana-Antezana

Emerald Coast Neurology

Recruiting

Pensacola, Florida, 32514, United States

Phone: 850-438-1136

David Bear

Velocity Clinical Research

Recruiting

Raleigh, North Carolina, 27607, United States

Phone: 919-719-8826

Casey Farin

Neurology of Central FL Res Ctr

Recruiting

Altamonte Springs, Florida, 32714, United States

Phone: 407-790-4990

Alicia Cabrera

Radiant Research Chandler

Recruiting

Chandler,Arizona,85224,United States

Osman Salim

Memorial Healthcare

Recruiting

Owosso,Michigan,48867,United States

Jeanie Lynn Cote

Tranquil Clinical Research

Recruiting

Webster,Texas,77598,United States

Amber Christian

Phone: 713-906-6316

Email: amberc@tranquilityresearch.com

Razi Rashid

Neurology Associates PA

Recruiting

Maitland,Florida,32751,United States

Phone: +1 407 647 5996 #7

William David Honeycutt

Piedmont HealthCare

Recruiting

Charlotte,North Carolina,28210,United States

Phone: 704-664-8060

Matthew Carraro

Swedish Medical Center

Recruiting

Seattle,Washington,98122-4379,United States

Phone: 206-320-2200

Pavle Repovic

International Neurorehab Institute

Recruiting

Lutherville,Maryland,21093,United States

Phone: 410-828-4629

Daniel Becker

University of Mississippi Medical Center

Recruiting

Jackson,Mississippi,39216-4505,United States

Phone: 888-815-2005

Mary Willis

University Of South Florida

Recruiting

Tampa,Florida,33612,United States

Phone: 813-974-6378

John Ciotti

Clinical Trial Network

Recruiting

Houston,Texas,77074,United States

Djamchid Lotfi

Santiago Rios

Email: srios@cntexas.com

Alabama Neurology Associates PC

Recruiting

Birmingham,Alabama,35209,United States

Emily Sherill Riser

S And D Clinical Research

Recruiting

Cape Coral,Florida,33904,United States

Phone: 239-722-9733

Jorge Diaz

Sentara Neuroscience Institute

Recruiting

Virginia Beach,Virginia,23456,United States

Phone: 757-507-0642

Michelle Betz-Kuczma

SUNY Upstate Medical Center

Recruiting

Syracuse,New York,13210,United States

Corey McGraw

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

Novartis Pharmaceuticals

Phone: +41613241111

Email:

Novartis Pharmaceuticals

Phone: 1-888-669-6682

Email: novartis.email@novartis.com

Source URL: <https://prod1.novartis.com/clinicaltrials/study/nct05090371>

List of links present in page

1. <https://clinicaltrials.gov/ct2/show/NCT05090371>
2. [#trial-eligibility](#)
3. <tel:843-851-7098>
4. <tel:407-352-5434>
5. <mailto:Tiffany.gilliard@orlandohealth.com>
6. <tel:208-625-5273>
7. <tel:806-722-3500>

8. tel:305-246-0873
9. tel:920-288-8100
10. tel:480-210-8723
11. tel:919-945-4752
12. tel:508-368-3168
13. mailto:candace.leblanc@reliantmedicalgroup.org
14. tel:256-739-1210
15. tel:865-218-6222
16. tel:313-556-8186
17. tel:432-368-2138
18. tel:414-955-0693
19. tel:949-547-6875
20. tel:732-776-4782
21. tel:425-899-5385
22. tel:318-769-2862
23. tel:850-438-1136
24. tel:919-719-8826
25. tel:407-790-4990
26. tel:713-906-6316
27. mailto:amberc@tranquilityresearch.com
28. tel:+1 407 647 5996 #7
29. tel:704-664-8060
30. tel:206-320-2200
31. tel:410-828-4629
32. tel:888-815-2005
33. tel:813-974-6378
34. mailto:srios@cntexas.com
35. tel:239-722-9733
36. tel:757-507-0642
37. tel:+41613241111
38. mailto:
39. tel:1-888-669-6682
40. mailto:novartis.email@novartis.com