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

Last Update: Jan 22, 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
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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

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