A Non-interventional Study Evaluating Clinical Utility and Implications on Improved Patient Management of Serum Neurofilament as a Prognostic Marker for Disease Activity in Patients With Relapsing Multiple Sclerosis

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A Non-interventional Study Evaluating Clinical Utility and Implications on Improved Patient Management of Serum Neurofilament as a Prognostic Marker for Disease Activity in Patients With Relapsing Multiple Sclerosis (FILAXOS)
ClinicalTrials.gov Identifier:
NCT06551519
Novartis Reference Number:COMB157GDE04
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 is a prospective, multicenter, observational, non-interventional study (NIS) in patients with Multiple Sclerosis (MS) and routinely assessed serum neurofilament light (sNfL) values in Germany Prospective, primary data will be collected from patients with sNfL outcomes in the context of switching to ofatumumab or continuing their current therapy. Data collection will cover a maximum period of 24 months.

The observational period will not be dictated by the protocol. Baseline and follow-up visits will take place at a frequency defined as per Investigator´s discretion following clinical routine. The diagnostic or monitoring procedures are only those ordinarily applied to therapeutic strategy and routine clinical care. During the observation phase of the study, data will be collected according to standard of care as recommended by KKNMS (Competence Network Multiple Sclerosis in Germany).

Eligible participants for the study are patients who have received treatment with category 1 DMTs and those who have included sNfL into their treatment decision-making process. These patients have the option to either continue their current DMT or switch to ofatumumab. According to local treatment guidelines, DMT category 1 include dimethylfumarate/diroximelfumarate, glatirameroids, Interferon beta and teriflunomide. The decision to switch to ofatumumab or to continue the current DMT category 1 therapy must be made by the treating physician independently of the decision to enroll the patient in the study.

Condition
Multiple Sclerosis
Overall Status
Recruiting

Number of Participants
900
Start Date
Oct 23, 2024
Completion Date
Sep 16, 2027
Gender
All
Age(s)
18 Years - 99 Years (Adult, Older Adult)

Interventions

Other

DMT category 1

This is an observational study. There is no treatment allocation. The decision to continue their current DMT will be based solely on clinical judgement.
Other

ofatumumab

This is an observational study. There is no treatment allocation. The decision to initiate ofatumumab will be based solely on clinical judgement.

Eligibility Criteria

Inclusion Criteria:

Participants eligible for inclusion in this study must meet all the following criteria:

1. Written informed consent must be obtained before participation in the study.
2. RMS patients aged 18 or older.
3. Treated in label with EU-approved DMTs for MS category 1 according to current guidelines (Hemmer et al 2023) for at least the last 3 months.
4. Presence of a sNfL test result from a commercially available test not older than 3 months.

Exclusion Criteria:

Participants meeting any of the following criteria are not eligible for inclusion in this study:

1. Patients being treated outside of the approved label of the respective DMT.
2. Simultaneous participation in any interventional study or simultaneous participation in another Novartis-sponsored non-interventional study with ofatumumab.

Germany

Novartis Investigative Site

Recruiting

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Recruiting

Muenchen,81675,Germany

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