Early Versus Late Ofatumumab (Kesimpta®) Use in Austrian RMS-Patients Over 2 Years

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Early Versus Late Ofatumumab (Kesimpta®) Use in Austrian RMS-Patients Over 2 Years- A Non-interventional Observational Study
ClinicalTrials.gov Identifier:
NCT05776888
Novartis Reference Number:COMB157GAT02
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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 non-interventional study aims to observe the effect of early versus late Ofatumumab treatment in RMS patients in a real-world setting in Austria over an observational period of 24 months. This multi-center, observational study will describe the effects of Ofatumumab in 2 cohorts in a routine medical care setting. Cohort one will comprise patients who have started Ofatumumab early during their disease (treatment naive patients or those that started Ofatumumab within 3 years of first therapy initiation). Cohort two will include patients who have been on other DMTs (one or several) for a minimum of 3 years prior to switching to Ofatumumab. Patients in both cohorts will be observed for two years.

Condition
Relapsing Multiple Sclerosis
Overall Status
Recruiting
Number of Participants
100
Start Date
Jul 10, 2023
Completion Date
Aug 31, 2026
Gender
All
Age(s)
18 Years - 99 Years (Adult, Older Adult)

Interventions

Other

Ofatumumab

There is no treatment allocation. For both cohorts, only patients that have received Ofatumumab treatment for at least 3 months prior to inclusion in the study will be enrolled.

Eligibility Criteria

Inclusion Criteria:

1. Patients with relapsing multiple sclerosis (RMS) with disease activity defined by clinical assessment or MRI analysis.
2. Written informed consent must be obtained before participating in the study.
3. Patient is willing and able to complete the assessments, as outlined in this study.
4. Diagnosis of RMS per McDonald Criteria (2017) occurred prior to initiation of Ofatumumab.
5. Patients in both cohorts must have been on treatment with Ofatumumab for at least 3 months, but not longer than 12 months prior to inclusion in the study.
6. Cohort 1: Patients that, before initiation of Ofatumumab, were either treatment naive or have started their treatment for RMS with another disease modifying therapy (BRACE, teriflunomide or fumarates). Non-naive patients in this cohort must have started the use of Ofatumumab within 3 years after first DMT initiation.
7. Cohort 2: Patients must have been on either BRACE or Teriflunomide or fumarates for at least three years or longer before the switch to Ofatumumab has been initiated. Thus, this cohort includes patients that use Ofatumumab as second or later line DMT.

Exclusion Criteria:

1. Patients who have been on Ofatumumab less than 3 months or more than 12 months before inclusion.
2. Use of investigational drugs during the study, OR between Ofatumumab initiation and inclusion into the study, OR within 5 half-lives of investigational drug before Ofatumumab initiation, OR until the expected pharmacodynamic effect has returned to baseline, whichever is longer.
3. Use of any high efficacy therapy (including Fingolimod, Siponimod, Ponesimod, Ozanimod, Rituximab, Ocrelizumab, Natalizumab, Alemtuzumab, Mitoxantron or Cladribine) in either cohort prior to the initiation of Ofatumumab.
4. Previous use of any DMTs other than BRACE, Teriflunomide or fumarates prior to the initiation of Ofatumumab.

Austria

Novartis Investigative Site

Recruiting

Vienna,A 1090,Austria

Novartis Investigative Site

Recruiting

Mistelbach,2130,Austria

Worldwide Contacts

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

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