Ofatumumab in Portuguese Multiple Sclerosis Patients - an Observational Study

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ClinicalTrials.gov Identifier:
NCT05809986
Novartis Reference Number:COMB157GPT04
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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 will compare the effect of Ofatumumab treatment between patients that began Ofatumumab within the 3 years after Multiple Sclerosis diagnosis and patients that began Ofatumumab with more than 3 years of Multiple Sclerosis diagnosis in a real-world setting in Portugal. This is a 2 cohort, multi-center, observational study carried out in Portugal that aims to describe the effectiveness of Ofatumumab in a setting of routine medical care. Primary data will be collected from Multiple Sclerosis patients who initiate Ofatumumab early and later in their disease (cohorts 1 and 2, respectively).

Data will be collected during 3 visits distributed over a maximum period of 24 months. Exceptionally, if the patient shows Expanded Disability Status Scale (EDSS) worsening in visit 2 or 3 (12 and 24 months after Ofatumumab initiation, respectively), there will be an additional visit 6±1 months after visit 2 or 3 for EDSS confirmation.

The study includes patients that have initiated Ofatumumab up to 12 months prior inclusion in the study OR Patients that are initiating Ofatumumab at the moment of study inclusion.

Patients in both cohorts will have to be treated with Ofatumumab for at least two years to compare No Evidence of Disease Activity (NEDA)-3 at 12 to 24 months, respectively.

Condition
Relapsing Multiple Sclerosis
Overall Status
Recruiting
Number of Participants
174
Start Date
Nov 27, 2023
Completion Date
Sep 15, 2026
Gender
All

Age(s)
18 Years - 99 Years (Adult, Older Adult)

Interventions

Other

Ofatumumab

There is no treatment allocation. Ofatumumab will be prescribed by the physician as per locally approved label. No drug will be dispensed from Novartis

Eligibility Criteria

Inclusion Criteria:

To participate in the study, all the following inclusion criteria must be met:

* Patients aged 18 years or older
* Written informed consent obtained before participating in the study.
* Patient is willing and able to complete the assessments, including PRO questionnaires, as outlined in this study.
* Diagnosis of RMS per McDonald Criteria (2017) occurred prior to initiation of Ofatumumab.
* Treatment with Ofatumumab is in accordance with the Portuguese indication of Kesimpta® (i.e., treatment of adult patients with relapsing multiple sclerosis (RMS) with active disease defined by clinical or imaging features).
* Patients that have initiated Ofatumumab up to 12 M prior inclusion in the study OR Patients that are initiating Ofatumumab at the moment of study inclusion.

Exclusion Criteria:

To participate in the study, none of the following exclusion criteria must be met:

* 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.
* Use of high efficacy therapy (including Ocrelizumab, Natalizumab, Mitoxantrone, Rituximab and Alemtuzumab) in both cohorts prior to the initiation of Ofatumumab.

Portugal

Novartis Investigative Site

Recruiting

Matosinhos,4454 513,Portugal

Novartis Investigative Site

Recruiting

Lisboa,1349-019,Portugal

Novartis Investigative Site

Recruiting

Ponte de Lima,4990 041,Portugal

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Recruiting

Amadora,2720-276,Portugal

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Recruiting

Porto,4200 319,Portugal

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Recruiting

Guimaraes,4835-044,Portugal

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Recruiting

Setubal,2910-446,Portugal

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Recruiting

Leiria,2410-104,Portugal

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Recruiting

Lisboa,1169 050,Portugal

Novartis Investigative Site

Recruiting

Lisboa,1649 035,Portugal

Worldwide Contacts

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

below.

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct05809986*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT05809986
2. #trial-eligibility
3. tel:+41613241111
4. mailto:novartis.email@novartis.com