ITAKOS - Italian Observation, Multicenter, Prospective Study of Ofatumumab in RRMS Patients

Last Update: Jan 14, 2025

An ITAlian Observational, Multicenter, 12-month, Single-arm Study to Evaluate the Effectiveness and Safety of Treatment With Ofatumumab (Kesimpta®) in a pOpulation of RRMS Patients in a Real-world Setting - the ITAKOS Study

ClinicalTrials.gov Identifier:
NCT06345157

Novartis Reference Number:COMB157GIT02

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

Study to evaluate the effectiveness of ofatumumab in Italian RRMS patients in the real-life setting. Prospective real-world data on ofatumumab is still very limited. For this reason, the main aim of this study is to investigate the impact of ofatumumab in a population of Italian RRMS patients in routine clinical practice to evaluate if ofatumumab is able in these conditions to provide relevant clinical benefits that comprehensively encompass anti-inflammatory activity (relapses), disability accumulation, cognitive impairment, fatigue symptoms and quality of life.

This is an observational, multicenter, single-arm, prospective study. Prospective data will be collected on patients newly treated with ofatumumab over an observational period of 12 months.

Condition
Multiple Sclerosis, Relapsing-Remitting
Overall Status
Recruiting
Number of Participants
300
Start Date
Jul 30, 2024
Completion Date
Jun 30, 2026
Gender
All
Age(s)
18 Years - 99 Years (Adult, Older Adult)

Interventions

Drug

Ofatumumab

This is an observational study. There is no treatment allocation. The decision to initiate treatment with ofatumumab (Kesimpta®) will be based solely on clinical judgement and according to the SmPC and AIFA reimbursement criteria.

Eligibility Criteria

Inclusion Criteria:

1. Male or female outpatients ≥18 years old.
2. Patients diagnosed with RRMS (McDonald criteria 2017).
3. Patients newly treated with ofatumumab, for whom the decision to start treatment with the drug has already been taken independently from study inclusion, based on clinical practice and according to the SmPC and to AIFA reimbursement criteria and who already successfully qualified for treatment with ofatumumab (i.e., passed the screening procedure mandated by the SmPC and the Risk Management Plan (RMP) for this treatment).
4. Patient or a legal representative of the patient must provide written informed consent before any study assessment is performed.

Exclusion Criteria:

1. Patients outside the approved label of ofatumumab.
2. Pregnant and lactating women.
3. Patients with any clinical condition that may interfere with the subject's ability to cooperate and comply with the study procedures based on investigator's judgement.
4. Patients cannot participate in this non-interventional study if they also participate in an interventional trial.
5. Treatment with ofatumumab prior to inclusion in this study or after 7 days from baseline visit.

Italy

Novartis Investigative Site

Recruiting

Trento,TN,38100,Italy

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Recruiting

Napoli,80138,Italy

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Recruiting

Palermo,PA,90127,Italy

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Recruiting

Catanzaro,CZ,88100,Italy

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Genova,GE,16132,Italy

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