

Evaluation of autonomy and care experience in multiple sclerosis when initiating subcutaneous ocrelizumab

Submission date 27/01/2026	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/01/2026	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/02/2026	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Multiple sclerosis (MS) can significantly impact a patient's autonomy and quality of life. This study, called PEACE, observes patients with Relapsing-Remitting MS (RRMS) who are starting a new treatment formulation: ocrelizumab injected subcutaneously (under the skin). The main aim is to understand how this treatment affects patients' satisfaction, autonomy, and daily symptoms in a real-world setting.

Who can participate?

Patients aged 18 years and over diagnosed with RRMS in France for whom their doctor has decided to prescribe subcutaneous ocrelizumab.

What does the study involve?

Participants will follow their standard medical care. In addition, they will complete questionnaires on a smartphone or computer about their quality of life, symptoms, and treatment satisfaction before their first injection and then every 6 months for 2 years.

What are the possible benefits and risks of participating?

As this is an observational study where patients receive standard care prescribed by their doctor, there are no additional medical risks associated with the study itself. There is no direct benefit, but participation helps improve understanding of MS treatments.

Where is the study run from?

Roche (France)

When is the study starting and how long is it expected to run for?

February 2026 to February 2029

Who is funding the study?

Roche (France)

Who is the main contact?
Dr David Pau, david.pau@roche.com

Contact information

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Scientific, Public

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Additional identifiers

Study information

Scientific Title

Patient Evaluation of Autonomy and Care Experience in multiple sclerosis when initiating ocrelizumab SC in real-world settings: the PEACE study

Acronym

PEACE

Study objectives

The primary objective is to describe the evolution of Health-Related Quality of Life (HRQoL) in patients initiating ocrelizumab SC, specifically assessing treatment satisfaction, autonomy, symptoms, and general health state.

Secondary objectives include comparing HRQoL over time, describing clinical effectiveness (disability progression, inflammatory activity), and assessing safety/tolerability in real-world conditions.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 20/01/2026, Comite de Protection des Personnes Ouest VI (CPP) (CHU Morvan 2 avenue Foch Bâtiment 1, Brest, 29200, France; +33 (0)230338064; cpp.ouest6@chu-brest.fr), ref: 25.03134.000445

Primary study design

Observational

Secondary study design

Cohort study

Study type(s)

Health condition(s) or problem(s) studied

Relapsing-remitting multiple sclerosis (RRMS)

Interventions

Adult patients with RRMS initiating ocrelizumab SC (920 mg) as part of their routine clinical care will be observed for 24 months. Data will be collected via electronic Case Report Forms (eCRF) and Patient Reported Outcomes (ePROs). Clinical data and questionnaires are collected at baseline (Day 0) and at 6, 12, 18, and 24 months post-initiation. The study observes two cohorts: patients switching from other therapies (Cohort A) and treatment-naïve patients (Cohort B).

Intervention Type

Biological/Vaccine

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Ocrelizumab

Primary outcome(s)

1. Autonomy measured using the Multiple Sclerosis Autonomy Scale (MSAS) at baseline, 6, 12, 18 and 24 months
2. Multiple sclerosis symptoms measured using the SymptoMScreen score at baseline, 6,12,18 and 24 months
3. Health state measured using the EQ-5D-5L health state score at baseline, 6, 12, 18 and 24 months
4. Treatment satisfaction measured using the Treatment Satisfaction Questionnaire for Medication (TSQM) at baseline, 6, 12, 18 and 24 months

Key secondary outcome(s)

Completion date

28/02/2029

Eligibility

Key inclusion criteria

1. Diagnosis of RRMS according to the 2017 or 2024 revised McDonald criteria
2. Age 18 years or older
3. Initiation of ocrelizumab SC planned by the healthcare professional (either as a switch from specific prior therapies or in treatment-naïve patients)
4. Physically and cognitively able to complete the study questionnaires and tests
5. Possession of a smartphone, tablet, or computer with an internet connection
6. Non-opposition to participation and data processing

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

120 years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Administration of ocrelizumab SC not in accordance with the standard of care or the current Summary of Product Characteristics (SmPC).
2. Patient under guardianship or judicial protection.

Date of first enrolment

09/02/2026

Date of final enrolment

01/02/2027

Locations

Countries of recruitment

France

Sponsor information

Organisation

Roche (France)

ROR

<https://ror.org/01mqmer16>

Funder(s)

Funder type

Funder Name

Roche France

Alternative Name(s)

Roche

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

France

Results and Publications

Individual participant data (IPD) sharing plan

Upon study completion and publication, qualified researchers may request access to individual patient level clinical data. Request will have to be send to: data_sharing.france@roche.com

IPD sharing plan summary

Available on request