ISRCTN31489759 https://doi.org/10.1186/ISRCTN31489759

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

Submission date
27/01/2026

Recruitment status
Not yet recruiting

Registration date
27/01/2026

Overall study status
Ongoing

Last Edited
04/02/2026

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

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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