# An Observational Study to Determine the Incidence of Injection Reactions Among Patients With Multiple Sclerosis Treated With Ocrelizumab Subcutaneous

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Study Planned

## Administrative details

**EU PAS number**

EUPAS1000001057

**Study ID**

1000001057

**DARWIN EU® study**

No

**Study countries**

Argentina

Czechia

United Kingdom

United States

**Study description**

This study will be conducted in patients with multiple sclerosis (MS) in routine clinical care who have newly initiated treatment with ocrelizumab subcutaneous (SC).

**Study status**

Planned

# Research institutions and networks

## Institutions

### F. Hoffmann-La Roche

**First published:** 01/02/2024

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Institution

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Maruthi Vinjam

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**
Planned: 30/09/2026

**Study start date**
Planned: 27/01/2027

**Data analysis start date**
Planned: 28/02/2030

**Date of final study report**
Planned: 28/02/2031

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

F. Hoffmann-La Roche Ltd

## Study protocol

Protocol_-_BN45958_-_OCREVUS_-_version_1_-_Published_20Apr2026_Redacted.pdf (1.05 MB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

**Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

## Other study registration identification numbers and links

BN45958

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

**Study design:**

This study is a prospective, longitudinal, non-interventional, observational, single-arm cohort study in adult patients with multiple sclerosis (MS) who have newly initiated treatment with ocrelizumab SC.

**Main study objective:**

The aim of this study is to determine injection reactions (IRs) occurring within 48 hours after the first ocrelizumab SC injection, regardless of the assessment of causality or relatedness with ocrelizumab SC.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

OCREVUS

**Medicinal product name, other**

Ocrevus Zunovo

**Study drug International non-proprietary name (INN) or common name**

OCRELIZUMAB

**Anatomical Therapeutic Chemical (ATC) code**

(L04AG08) ocrelizumab

ocrelizumab

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**Medical condition to be studied**

Multiple sclerosis

# Population studied

**Short description of the study population**

Patients must have a diagnosis of multiple sclerosis and newly initiated treatment with ocrelizumab subcutaneous (SC) according to the local label, irrespective of the reason for starting ocrelizumab SC.

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**Age groups**

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

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**Estimated number of subjects**

400

# Study design details

**Setting**

Inclusion criteria:

• Have signed the informed consent

• Have a diagnosis of multiple sclerosis (MS)

• Aged 18 years or older at the time of study enrolment

• Have newly initiated treatment with ocrelizumab SC according to the local label, irrespective of the reason for starting ocrelizumab SC

• Have enrolled in the study (baseline visit completed and informed consent signed), with study enrolment date prior to or on the same day as the first administration of ocrelizumab SC.

Exclusion criteria:

• Patients who have any prior exposure to ocrelizumab or to any other anti-CD20 therapy given for MS

• Patients actively participating in interventional clinical trials for MS

• Patients with date of first administration of ocrelizumab SC before the study baseline enrolment date.

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**Outcomes**

Primary:

• Incidence proportion of injection reactions (IR) after first administration of ocrelizumab SC

Secondary:

• Incidence proportion of IR after second and subsequent administration of ocrelizumab SC

• Incidence proportion of local injection reactions (LIR)

• Incidence proportion of systemic injection reactions (SIR)

• Event rate of IR per patient per ocrelizumab SC injection

• Event rate of serious adverse events (SAEs) per patient per year at risk

**Data analysis plan**

The incidence proportion of IRs among patients exposed to ocrelizumab SC will be calculated, overall and by IR type (i.e. all IR, LIR, SIR), as the total number of first (i.e., incident) events divided by the total patients at risk. Total patients at risk will be calculated as the total number of patients exposed to ocrelizumab SC for whom the 48-hour follow-up information was successfully obtained. Exact binomial 95% CIs of the incidence proportion will be calculated using the Clopper-Pearson method.

To capture recurrent IRs, the event rate of IR will be reported as the number of IRs per patient per SC injection and computed as the total number of IRs (irrespective of the type, i.e. LIR, SIR) divided by the total number of ocrelizumab SC injections.

Secondary objective analysis endpoint - SAEs occurring within the study observation period, regardless of the assessment of causality or relatedness with ocrelizumab SC: For all SAEs other than IRs, event rates (both first incidence and recurrent SAEs) will be based on a time-on-drug approach that uses person-time as exposed from first ocrelizumab SC dose in the study up to 2 years after the first administration of ocrelizumab SC, death, loss to follow-up, or the end of the study, whichever occurs first. Exact Poisson 95% CIs of the rate will be calculated.

# Data management

# ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

# Data sources

**Data sources (types)**

Non-interventional study

# Use of a Common Data Model (CDM)

**CDM mapping**

No

# Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

Unknown