

Relapsing Multiple Sclerosis (RMS)

A Study of Subcutaneously Administered RO7845860 in Participants With Relapsing Multiple Sclerosis

Trial Status
Not yet recruiting

Trial Runs In

Trial Identifier
NCT07749157 2026-526353-34-00
BP46580

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

An Open-Label, Multicenter, Dose Escalation Study to Investigate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Subcutaneously Administered RO7845860 in Participants With Relapsing Multiple Sclerosis

Trial Summary:

The purpose of this study is to assess the safety, tolerability, pharmacokinetics (PK) and, pharmacodynamics (PD) of subcutaneously administered RO7845860 in participants with relapsing multiple sclerosis (RMS).

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT07749157 2026-526353-34-00 BP46580
Trial Identifiers

Eligibility Criteria:

Gender All	Age #18 Years & # 60 Years	Healthy Volunteers No
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Inclusion Criteria:

- Diagnosis of RMS (i.e., relapsing-remitting multiple sclerosis [RRMS] or a secondary progressive multiple sclerosis [SPMS] where patients still experience relapses) in accordance with the revised 2017 McDonald Criteria.
- No relapse for 30 days prior to screening and neurologically stable with no relapse during screening.
- Expanded Disability Status Scale (EDSS) score at screening (historical EDSS not older than 6 months may be used), from 0 to 6.5 inclusive.

ForPatients

by Roche

- From Part 2 onwards,
- at least two documented clinical relapses within the last 2 years prior to screening, or
- one documented clinical relapse in the year prior to screening or
- one documented clinical relapse together with signs of Magnetic Resonance Imaging (MRI) activity (any T1 Gd+ and/or new or enlarging T2 lesion) between 12 and 24 months prior to screening.
- Documented MRI of brain with abnormalities consistent with Multiple Sclerosis (MS) at screening.

Exclusion Criteria:

- History of primary progressive multiple sclerosis (PPMS) at screening.
- Any of the following laboratory parameters:
 - CD4 levels below lower limit of normal (LLN)
 - Absolute neutrophil count (ANC) levels below LLN
 - Serum immunoglobulin G (IgG) levels below LLN
 - Absolute lymphocyte count < 1000 cells per microliter (µL)
 - B-cell levels below LLN
- Known presence of other neurologic disorders that may mimic MS, including but not limited to, neuromyelitis optica spectrum disease, myelin oligodendrocyte antibody associated disease, Lyme disease, untreated vitamin B-12 deficiency, cerebrovascular or spinal vascular disorders, and untreated hypothyroidism.
- Clinically significant cardiac, metabolic, hematologic, hepatic, immunologic, urologic, endocrinologic, neurologic, pulmonary, dermatologic, psychiatric, allergic, renal or other major diseases that in the investigator's judgement, may affect interpretation of study results or participant safety.
- Prior treatment with Chimeric antigen receptor (CAR) T-cell therapy, gene-therapy product, total body irradiation, bone marrow transplantation, allograft organ transplant, or hematopoietic stem cell transplant at any point.
- Inability to complete an MRI scan (contraindications for MRI, including but not restricted to, pacemaker, cochlear implants, intracranial vascular clips, surgery within 6 weeks prior to screening coronary stent implanted within 8 weeks prior to the time of the intended MRI, etc.) or contraindication to gadolinium administration.