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Impact of ocrelizumab on patient-reported fatigue and quality of life in participants with relapsing multiple sclerosis treated for the first time with ocrelizumab

Submission date
14/10/2021

Recruitment status
No longer recruiting

Registration date
02/11/2021

Overall study status
Ongoing

Last Edited
03/12/2024

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Relapsed multiple sclerosis (RMS) is a complex disease in which the insulating layer of nerves (the myelin layer) breaks down and disturbs communication between nerve cells. This study aims to collect data on initial treatment with Ocrevus® from the routine care of patients with RMS and to analyze it.
Ocrevus® is used to treat RMS and early primary progressive multiple sclerosis (PPMS) in adult patients. Ocrevus® contains the active ingredient ocrelizumab. It is a specific type of protein called a monoclonal antibody. Antibodies work by attaching themselves to bind certain targets in the body. Ocrevus® binds to certain B cells, a type of white blood cell that is part of the immune system and plays a role in multiple sclerosis. Ocrevus® targets these specific B cells and removes them. This reduces inflammatory processes and attacks on the myelin layer, making relapse less likely to occur and slowing disease progression. Knowledge of this medicinal product can be expanded in patients with RMS and may influence long-term treatment with Ocrevus®.

Who can participate?
Patients aged between 18 years and 65 years with relapsed multiple sclerosis being treated with ocrelizumab (Ocrevus®) for the first time

What does the study involve?
The following data will be collected over a period of 2 years:
1. Demographic data: year of birth, gender
2. Employment level
3. Medical history and other illnesses, including medical and surgical history
4. History of MS disease and treatment
5. Date of first symptoms of MS and type of symptoms
6. Date of MS diagnosis and type of symptoms at diagnosis
7. Confirmation of the RMS diagnosis

8. Number of relapses per year within the last 3 years
9. All previous MS treatments and therapies, including duration and the main reason for discontinuation (if any)
10. MS status before the start of treatment
11. Magnetic resonance imaging (MRI) results within the last 12 months
12. All previous and accompanying immunomodulatory and immunosuppressive treatments including their duration
13. Any previous and accompanying medication to treat tiredness and/or depression including its dose
14. Any previous and accompanying medication within the last 3 months, especially drugs that can cause fatigue (e.g. antihistamines)
15. MS symptoms, relapses, MS type, as well as MS status and MRI since the last visit (if present)
16. Physical and mental activities (e.g. endurance and strength training)
17. State of health (e.g. smoking habits)
18. Vital signs (blood pressure, heart rate, body temperature), height and weight
19. Laboratory values: blood tests (blood count, chemistry, immunoglobulins, kidney values), data on certain immune cells (B-cell status), data on the menopause status, test for bacterial and viral infections
20. Treatment with Ocrevus® (dose, duration of infusion, type of pre-medication)
21. Questionnaire to assess the severity of the permanently increased exhaustion before the premedication of Ocrevus®
22. Evaluation of the severity of the daily form-dependent increased exhaustion before the premedication, after the pre-medication, after the Ocrevus® infusion, 2 days after the infusion (at home), and 3 months after the infusion (at home)
23. Questionnaire on the influence that multiple sclerosis has on everyday life
24. Questionnaire on impairment of work productivity and activity
25. Questionnaire to assess anxiety and depression in participants with physical diseases
26. Questionnaire for recording mental deficits
27. Serious and non-serious adverse events after the first dose of Ocrevus®, as well as reactions that occur with the procedure of infusion in related adverse events of special interest (i.e. cases of drug-induced liver damage, suspected transmission of infectious material through the study medication)
28. Date of last contact with the attending doctor
29. To assess the impact of any digital health applications (DiGA) app use on fatigue (not applicable for participants in Switzerland)

What are the possible benefits and risks of participating?
Research projects have confidentiality risks (e.g. the possibility of identifying the participant). There is no benefit to participants from providing this data, but the findings from this study may be used to improve long-term treatment with Ocrevus® in the future.

Where is the study run from?
Katholisches Klinikum Lünen/Werne GmbH (Germany)

When is the study starting and how long is it expected to run for?
November 2020 to June 2026

Who is funding the study?
1. Roche Pharma AG (Germany)
2. Roche Pharma (Schweiz) AG (Switzerland)

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ML42393

Study information

Scientific Title
Impact of ocrelizumab on patient-reported fatigue and quality of life in relapsing multiple sclerosis patients treated for the first time with ocrelizumab (MoOzaRt): an observational study

Acronym
NIS MoOzaRt

Study objectives
To assess the impact of ocrelizumab on patient-reported fatigue over a period of time (trait), but also at the moment of treatment (state) and the impact of other parameters, such as cognition or quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/08/2021, Ethics Board of the State Medical Council of Baden-Württemberg (Liebknechtstr. 33, 70565 Stuttgart, Germany; +49 (0)711 76989 0; ethikkommission@laek-bw.de), ref: ML42393

Study design
Multicenter non-interventional (NIS) primary data collection study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple sclerosis (MS)

Interventions
Current interventions as of 28/11/2024:

The treatment follows the Summary of Product Characteristics (SmPC). The initial dose of 600 milligrams (mg) ocrelizumab (Ocrevus®) is given as two separate intravenous (IV) infusions; a first infusion of 300 mg followed by a second infusion of 300 mg given 2 weeks later. Follow-up doses of ocrelizumab are given as single intravenous infusions of 600 mg every 6 months. The first 600 mg follow-up dose should be given 6 months after the first infusion of the initial dose. For participants who switch from IV infusion to subcutaneous (SC) injection of ocrelizumab after the initial infusions or later, the first SC dose of 920 mg should be given six months after the last infusion. Thereafter, a minimum interval of 5 months must be observed between each dose of ocrelizumab (IV or SC).

During the 24-month observation period, participants will be assessed at the screening visit (V0) and during visits performed at month 0 (baseline, V1), around month 6 (V2), around month 12 (V3), around month 18 (V4) and around month 24 (V5, final) corresponding to routine clinical practice. Screening and baseline assessments can be performed on the same day as the first initial dose of ocrelizumab is given. Collection of Patient-Reported Outcomes (PROs) is based on the completion of questionnaires and scales by the participants using the electronic PRO system. The usage of PROs is considered non-interventional according to local regulations. “Trait fatigue” is measured at the first initial ocrelizumab infusion (baseline) and at the other visits with ocrelizumab treatment using the Fatigue Scale for Motor and Cognitive Functions (FSMC) (five assessments of “trait fatigue” expected per participant in the whole observation period). “State fatigue” is assessed by Visual Analogue Scale (VAS) three times at each visit with ocrelizumab infusion, once before, once after premedication, and once after ocrelizumab infusion. Additionally, “state fatigue” is analyzed using the electronic PRO 2 days after infusion and 3 months after each infusion visit. At month 24, the last “state fatigue” assessment is performed 2 days after infusion (24 assessments of “state fatigue” expected per participant in the observation period). PROs are recorded at the first initial dose and the four infusion visits (V2-V5, five assessments expected per participant in the observation period). Collection of PROs include completion of the questionnaires/scales Multiple Sclerosis Impact Scale - 29(MSIS-29), Work Productivity and Activity Impairment Questionnaire: Multiple Sclerosis (WPAI:MS), Hospital Anxiety and Depression Scale (HADS), and Perceived Deficits Questionnaire (PDQ-20). Further parameters, such as Expanded Disability Status Scale (EDSS), MS relapses, change of MS treatment, employment status, physical fitness, health condition (e.g., smoking habit), premedication (e.g., type of antihistamine), laboratory values (e.g., ferritin, Hemoglobin (HB) value) and use of digital health applications (DiGA) apps for MS participants with fatigue (not applicable for participants in Switzerland), as available, are recorded at each treatment.

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Previous interventions as of 20/12/2023:

The treatment follows the Summary of Product Characteristics (SmPC). The initial dose of 600 mg ocrelizumab (Ocrevus®) is given as two separate intravenous infusions; a first infusion of 300 mg followed by a second infusion of 300 mg given 2 weeks later. Follow-up doses of ocrelizumab are given as single intravenous infusions of 600 mg every 6 months. The first 600 mg follow-up dose should be given 6 months after the first infusion of the initial dose.

During the 24-month observation period, participants will be assessed at the screening visit (V0) and during visits performed at month 0 (baseline, V1), around month 6 (V2), around month 12 (V3), around month 18 (V4) and around month 24 (V5, final) corresponding to routine clinical practice. Screening and baseline assessments can be performed on the same day as the first initial dose of ocrelizumab is given. Collection of Patient-Reported Outcomes (PROs) is based on the completion of questionnaires and scales by the participants using the electronic PRO system. The usage of PROs is considered non-interventional according to local regulations. “Trait fatigue” is measured at the first initial ocrelizumab infusion (baseline) and at the other visits with ocrelizumab infusion using the Fatigue Scale for Motor and Cognitive Functions (FSMC) (five assessments of “trait fatigue” expected per participant in the whole observation period). “State fatigue” is assessed by Visual Analogue Scale (VAS) three times at each visit with ocrelizumab infusion, once before, once after premedication, and once after ocrelizumab infusion. Additionally, “state fatigue” is analyzed using the electronic PRO 2 days after infusion and 3 months after each infusion visit. At month 24, the last “state fatigue” assessment is performed 2 days after infusion (24 assessments of “state fatigue” expected per participant in the observation period). PROs are recorded at the first initial dose and the four infusion visits (V2-V5, five assessments expected per participant in the observation period). Collection of PROs include completion of the questionnaires/scales Multiple Sclerosis Impact Scale (MSIS-29), Work Productivity and Activity Impairment Questionnaire: Multiple Sclerosis (WPAI:MS), Hospital Anxiety and Depression Scale (HADS), and Perceived Deficits Questionnaire (PDQ-20). Further parameters, such as Expanded Disability Status Scale (EDSS), MS relapses, change of MS treatment, employment status, physical fitness, health condition (e.g., smoking habit), premedication (e.g., type of antihistamine), laboratory values (e.g., ferritin, Hemoglobin (HB) value) and use of digital health applications (DiGA) apps for MS participants with fatigue (not applicable for participants in Switzerland), as available, are recorded at each infusion.

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Previous interventions:

The treatment follows the Summary of Product Characteristics (SmPC). The initial dose of 600 mg ocrelizumab (Ocrevus®) is given as two separate intravenous infusions; a first infusion of 300 mg followed by a second infusion of 300 mg given 2 weeks later. Follow-up doses of ocrelizumab are given as single intravenous infusions of 600 mg every 6 months. The first 600 mg follow-up dose should be given 6 months after the first infusion of the initial dose.

During the 24-month observation period, patients will be assessed at the screening visit (V0) and during visits performed at month 0 (baseline, V1), around month 6 (V2), around month 12 (V3), around month 18 (V4) and around month 24 (V5, final) corresponding to routine clinical practice. Screening and baseline assessments can be performed on the same day as the first initial dose of ocrelizumab is given. Collection of Patient-Reported Outcomes (PROs) is based on the completion of questionnaires and scales by the patients using the electronic PRO system. The

usage of PROs is considered non-interventional according to local regulations. “Trait fatigue” is measured at the first initial ocrelizumab infusion (baseline) and at the other visits with ocrelizumab infusion using the Fatigue Scale for Motor and Cognitive Functions (FSMC) (five assessments of “trait fatigue” expected per patient in the whole observation period). “State fatigue” is assessed by Visual Analogue Scale (VAS) three times at each visit with ocrelizumab infusion, once before, once after premedication, and once after ocrelizumab infusion. Additionally, “state fatigue” is analyzed using the electronic PRO 2 days after infusion and 3 months after each infusion visit. At month 24, the last “state fatigue” assessment is performed 2 days after infusion (24 assessments of “state fatigue” expected per patient in the observation period). PROs are recorded at the first initial dose and the four infusion visits (V2-V5, five assessments expected per patient in the observation period). Collection of PROs include completion of the questionnaires/scales Multiple Sclerosis Impact Scale (MSIS-29), Work Productivity and Activity Impairment Questionnaire: Multiple Sclerosis (WPAI:MS), Hospital Anxiety and Depression Scale (HADS), and Perceived Deficits Questionnaire (PDQ-20). Further parameters, such as Expanded Disability Status Scale (EDSS), MS relapses, change of MS treatment, employment status, physical fitness, health condition (e.g., smoking habit), premedication (e.g., type of antihistamine), laboratory values (e.g., ferritin, Hemoglobin (HB) value) and use of digital health applications (DiGA) apps for MS patients with fatigue as available, are recorded at each infusion.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Ocrelizumab

Primary outcome(s)
Current primary outcome measure as of 28/11/2024:

"Trait fatigue" in RMS participants treated for the first time with ocrelizumab measured using the FSMC total score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months

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Previous primary outcome measure as of 20/12/2023:

"Trait fatigue" in relapsed multiple sclerosis (RMS) participants treated for the first time with ocrelizumab measured using the FSMC total score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months

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Previous primary outcome measure:

"Trait fatigue" in relapsed multiple sclerosis (RMS) patients treated for the first time with ocrelizumab measured using the FSMC total score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months

Key secondary outcome(s))

Current secondary outcome measures as of 28/11/2024:

1. “Trait fatigue” in RMS participants treated for the first time with ocrelizumab, measured by the FSMC cognitive score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
2. “Trait fatigue” in RMS participants treated for the first time with ocrelizumab, measured by the FSMC motor score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
3. “Trait fatigue” in RMS participants treated for the first time with ocrelizumab with a clinically meaningful reduction of ≥9 points using the FSMC total score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
4. Change in “State fatigue” from before to during and after the treatment with ocrelizumab in participants with RMS measured by VAS over a time of 24 months observation period
5. Quality of life assessed using MSIS-29 at baseline and over the 24-month observation period
6. Working productivity and activity assessed using WPAI:MS at baseline and over the 24-month observation period
7. Depression assessed using HADS at baseline and over the 24-month observation period
8. Cognition assessed using PDQ-20 at baseline and over the 24-month observation period
9. Correlation of “trait fatigue” (FSMC total score, cognitive score, motor score) with PROs(MSIS-29, WPAI:MS, HADS, PDQ-20) analyzed using Pearson or Spearman correlation coefficients over the 24-month observation period.
10. Correlation of “trait fatigue” (FSMC total score, cognitive score, motor score) with non-serious adverse events (nsAEs), serious adverse events (SAEs) and adverse events of special interests (AESIs) that occurred during fatigue measurement assessed by PROs over the 24-month observation period
15. Correlation of “trait fatigue” (FSMC total score, cognitive score, motor score) with EDSS over the 24-month observation period

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Previous secondary outcome measures as of 20/12/2023:

1. “Trait fatigue” in RMS participants treated for the first time with ocrelizumab, measured by the FSMC cognitive score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
2. “Trait fatigue” in RMS participants treated for the first time with ocrelizumab, measured by the FSMC motor score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
3. “Trait fatigue” in RMS participants treated for the first time with ocrelizumab with a clinically meaningful reduction of ≥9 points using the FSMC total score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
4. “Trait fatigue” in RMS participants treated for the first time with ocrelizumab with a clinically meaningful reduction of ≥5 points using the FSMC cognitive score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
5. “Trait fatigue” in RMS participants treated for the first time with ocrelizumab with a clinically meaningful reduction of ≥4 points using the FSMC motor score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
6. “Trait fatigue” in RMS participants treated for the first time with ocrelizumab with a stabilization (=0 points) or reduction (of >0 points) using the FSMC total score, cognitive score and motor score, respectively, at baseline (i.e., before the first initial dose of ocrelizumab

treatment) and over a time period of 24 months
7. “Trait fatigue” in RMS participants treated for the first time with ocrelizumab measured using the FSMC total score, cognitive score and motor score, respectively, at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 12 months
8. “State fatigue” absolute change in RMS participants from baseline (before premedication) by visit, to after premedication, after ocrelizumab infusion, 2 days post-infusion and 3 months post infusions, measured by a Visual Analogue scale (VAS) and infusion time (2 h/2.5 h/3.5 h) will be presented for each ocrelizumab infusion.
9. Quality of life assessed using MSIS-29 at baseline and over the 24-month observation period
10. Working productivity and activity assessed using WPAI:MS at baseline and over the 24-month observation period
11. Depression assessed using HADS at baseline and over the 24-month observation period
12. Cognition assessed using PDQ-20 at baseline and over the 24-month observation period
13. Correlation of “trait fatigue” (FSMC total score, cognitive score, motor score) with PROs(MSIS-29, WPAI:MS, HADS, PDQ-20) analyzed using Pearson or Spearman correlation coefficients over the 24-month observation period.
14. Correlation of “trait fatigue” (FSMC total score, cognitive score, motor score) with adverse events (AEs) that occurred during fatigue measurement assessed by PROs over the 24-month observation period
15. Correlation of “trait fatigue” (FSMC total score, cognitive score, motor score) with EDSS over the 24-month observation period

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Previous secondary outcome measures as of 21/09/2022 to 20/12/2023:

1. “Trait fatigue” in RMS patients treated for the first time with ocrelizumab, measured by the FSMC cognitive score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
2. “Trait fatigue” in RMS patients treated for the first time with ocrelizumab, measured by the FSMC motor score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
3. “Trait fatigue” in RMS patients treated for the first time with ocrelizumab with a clinically meaningful reduction of ≥9 points using the FSMC total score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
4. “Trait fatigue” in RMS patients treated for the first time with ocrelizumab with a clinically meaningful reduction of ≥5 points using the FSMC cognitive score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
5. “Trait fatigue” in RMS patients treated for the first time with ocrelizumab with a clinically meaningful reduction of ≥4 points using the FSMC motor score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
6. “Trait fatigue” in RMS patients treated for the first time with ocrelizumab with a stabilization (=0 points) or reduction (of >0 points) using the FSMC total score, cognitive score and motor score, respectively, at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
7. “Trait fatigue” in RMS patients treated for the first time with ocrelizumab measured using the FSMC total score, cognitive score and motor score, respectively, at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 12 months
8. “State fatigue” absolute change in RMS patients from baseline (before premedication) by visit, to after premedication, after ocrelizumab infusion, 2 days post-infusion and 3 months post infusions, measured by a Visual Analogue scale (VAS) and infusion time (2 h/2.5 h/3.5 h) will be presented for each ocrelizumab infusion.

9. Quality of life assessed using MSIS-29 at baseline and over the 24-month observation period
10. Working productivity and activity assessed using WPAI:MS at baseline and over the 24-month observation period
11. Depression assessed using HADS at baseline and over the 24-month observation period
12. Cognition assessed using PDQ-20 at baseline and over the 24-month observation period

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Previous secondary outcome measures:

1. “Trait fatigue” in RMS patients treated for the first time with ocrelizumab, measured by the FSMC cognitive score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
2. “Trait fatigue” in RMS patients treated for the first time with ocrelizumab, measured by the FSMC motor score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
3. “Trait fatigue” in RMS patients treated for the first time with ocrelizumab with a clinically meaningful reduction of ≥9 points using the FSMC total score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
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5. “Trait fatigue” in RMS patients treated for the first time with ocrelizumab with a clinically meaningful reduction of ≥4 points using the FSMC motor score at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
6. “Trait fatigue” in RMS patients treated for the first time with ocrelizumab with a stabilization (=0 points) or reduction (of >0 points) using the FSMC total score, cognitive score and motor score, respectively, at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 24 months
7. “Trait fatigue” in RMS patients treated for the first time with ocrelizumab measured using the FSMC total score, cognitive score and motor score, respectively, at baseline (i.e., before the first initial dose of ocrelizumab treatment) and over a time period of 12 months
8. “State fatigue” absolute change in RMS patients from baseline (before premedication) by visit, to after premedication, after ocrelizumab infusion, 2 days post-infusion and 3 months post infusions, measured by a Visual Analogue scale (VAS) and infusion time (2 h/2.5 h/3.5 h) will be presented for each ocrelizumab infusion.

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 03/12/2024:

1. Diagnosis of MS
2. RMS participants, diagnosed by revised McDonald criteria
3. First-time treatment during the course of MS therapy with ocrelizumab according to the local label, regardless of the reason for starting treatment with ocrelizumab (participants may switch to the shorter IV infusion or SC injection within the study)

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Previous inclusion criteria:

1. Diagnosis of MS
2. RMS patients, diagnosed by revised McDonald criteria
3. First-time treatment during the course of MS therapy with ocrelizumab according to the local label, regardless of the reason for starting treatment with ocrelizumab (patients may switch to the shorter infusion within the study)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Off-label use of ocrelizumab
2. Participation in interventional studies investigating disease-modifying therapies for MS or in NIS Confidence (ML39632)
3. Severe psychiatric disability
4. Previous treatment with anti-CD20 antibodies
5. Pregnant and/or breastfeeding

Date of first enrolment
28/12/2021

Date of final enrolment
18/06/2024

Locations

Countries of recruitment
Germany

Switzerland

Study participating centre
Nervenfachärztliche Gemeinschaftspraxis Ulm
Pfauengasse 8
Ulm
Germany
89073

Study participating centre
MVZ Dres. Schöll/Steidl & Kollegen GbR
Bad Homburg
Germany
61348

Study participating centre
Neurologie Prenzlauer Berg
Dres. Claassen/Wontroba
Berlin
Germany
10437

Study participating centre
Praxisgemeinschaft Dres. Sylke Domke und Vasil Gjaurov
Chemnitz
Germany
09117

Study participating centre
Universitätsklinikum "Carl Gustav Carus", Zentrum für Klinische Neurowissenschaften
Dresden
Germany
01307

Study participating centre
Praxis Nervenstark; Essen-Kupferdreh
Essen
Germany
45257

Study participating centre

Universitätsklinikum Freiburg, Klinik für Neurologie und Neurophysiologie
Freiburg
Germany
79106

Study participating centre
MultipEL Studies - Institut für klinische Studien
Hamburg
Germany
22179

Study participating centre
Neurologische Gemeinschaftspraxis
Heidenheim
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Study participating centre
Universitätsklinikum Jena, Klinik für Neurologie
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Study participating centre
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Neuburg
Germany
86633

Study participating centre
Facharztpraxis für Neurologie und Psychiatrie Dres Mattes/Stockert
Pforzheim
Germany
75172

Study participating centre

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Germany
42853

Study participating centre
Neurologische Praxis Dr. Wagner
Schwetzingen
Germany
68723

Study participating centre
Klinikum Sindelfingen-Böblingen; Klinik für Neurologie
Sindelfingen
Germany
71065

Study participating centre
EMSA - Zentrum für Neurologie/Psychiatrie/Neuroradiologie
Singen
Germany
78224

Study participating centre
Praxis Dr. med. Andreas Kowalik, Arzt für Neurologie und Psychiatrie
Stuttgart
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Study participating centre
Neuropraxis München Süd
Unterhaching
Germany
82008

Study participating centre

Oberhavel Kliniken, Ambulantes MS Zentrum Hennigsdorf
Hennigsdorf
Germany
16761

Study participating centre
Universitätsklinikum Würzburg Neurologie
Würzburg
Germany
97080

Study participating centre
Neuroplus
Mannheim
Germany
68163

Study participating centre
SRH Waldklinikum
Gera
Germany
07548

Study participating centre
Uniklinik RWTH Aachen
Aachen
Germany
52074

Study participating centre
Klinikum Frankfurt Hochst GmbH
Frankfurt
Germany
65929

Study participating centre

Kbo-Isar amper-Klinikum
Haar
Germany
85540

Study participating centre
Gemeinschaftspraxis Dr. med. Reinhard Ehret/Dr. med Wolfram von Pannwitz
Berlin
Germany
12163

Study participating centre
Neuropraxis im Stadtpalais Dres. Ulzheimer/Herroder/Wessig GbR
Aschaffenburg
Germany
63739

Study participating centre
NeuroConcept AG C/O mind mvz GmbH
Stuttgart
Germany
70182

Study participating centre
St. Josefs-Krankenhaus Potsdam-Sanssouci GmbH
Potsdam
Germany
14471

Study participating centre
Gesundheitszentrum St. Johannes Hospital
Bonn
Germany
53111

Study participating centre

Universitätsklinikum Tübingen, Zentrum fur Neurologie
Tübingen
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72076

Study participating centre
Universitätsklinikum Mannheim
Mannheim
Germany
68167

Study participating centre
Universitäetsklinikum Frankfurt
Frankfurt
Germany
60528

Study participating centre
Praxis fur Neurologie und Psychiatrie am Prinzregentenplatz
München
Germany
81675

Study participating centre
Gesundheit Nord, Klinikum Bremen-Ost
Bremen
Germany
28235

Study participating centre
Katholisches Klinikum Lünen/Werne GmbH; Neurologische Klinik
Lünen
Germany
44534

Study participating centre

Universitaetsklinikum Marburg; Klinik fuer Neurologie
Marburg
Germany
35043

Study participating centre
Inselspital Bern Medizin Neurologie; Neurologische Poliklinik
Bern
Switzerland
3010

Study participating centre
Luzerner Kantonsspital Luzern Medizin Neurologie
Luzern
Switzerland
6004

Sponsor information

Organisation
Roche (Germany)

ROR
https://ror.org/00sh68184

Organisation
Roche (Switzerland)

ROR
https://ror.org/00by1q217

Funder(s)

Funder type
Industry

Funder Name
F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
Raw data for this study is not expected to be available; there is no regulatory requirement.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes