ForPatients
by Roche

Multiple Sclerosis (MS)

A clinical trial to find a safe and suitable dose of ocrelizumab in children and adolescents with relapsing-remitting multiple sclerosis

A Study of Ocrelizumab in Children and Adolescents With Relapsing-Remitting Multiple Sclerosis

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	3 Countries	NCT04075266 2016-002667-34 WA39085

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, Parallel-Group Study to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamic Effects of Ocrelizumab in Children and Adolescents With Relapsing-Remitting Multiple Sclerosis

Trial Summary:

This 2-year study will evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamic (PD) effects of ocrelizumab in children and adolescents ages # 10 to # 18 years with relapsing-remitting multiple sclerosis (RRMS). The data from this study will serve to determine the dosing regimen of ocrelizumab to be further investigated in the subsequent Phase III study in children and adolescents.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT04075266 2016-002667-34 WA39085
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#10 Years & # 18 Years	No

1. Why is the Operetta 1 clinical trial needed?

The purpose of this clinical trial is to test the safety of ocrelizumab at certain doses and to understand how the body processes it. The study will also identify the dose of ocrelizumab that is most appropriate to use in further trials in people under 18 years of age.

2. How does the Operetta 1 clinical trial work?

This clinical trial is recruiting children and young people who have a type of disease called relapsing-remitting multiple sclerosis (RRMS).

Young people who take part in this clinical trial (referred to as 'participants') will be given the clinical trial treatment ocrelizumab every 24 weeks for about 5.5 years. The clinical trial doctor will see them every 12 weeks with visits every 4 weeks in the first 6 months. These hospital visits will include checks to see how the participant responds to the treatment and any side effects they may have. The total time of participation in the clinical trial will be about 7 years including Screening and Safety Follow Up period after the study drug ends. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the Operetta 1 clinical trial?

The main clinical trial endpoints (the main results measured in the trial to see if the study drug has worked) will see how long ocrelizumab stays in the body for and at what strength. Also what ocrelizumab does to other blood cells in the body, in children and adolescents aged 10 years and above with RRMS.

The data from this study will determine the dose of ocrelizumab to be further investigated in another study in children and adolescents.

The other clinical trial endpoints include the safety of ocrelizumab in children and young people, and how their disease responds to ocrelizumab.

4. Who can take part in this clinical trial?

To be able to take part in this clinical trial, a person must have a diagnosis of RRMS, be aged 10 to 17 years, and have a body weight of at least 25 kg.

A person may not be able to take part in this trial if they have received previous B-cell targeted therapy.

5. What treatment will participants be given in this clinical trial?

Everyone who joins this clinical trial will be given ocrelizumab, given as an infusion (into the vein) every 24 weeks for 5.5 years. Participants will be given a dose based on their body weight.

- Group 1: participants who weigh between 25 and 39 kg, will be given a lower dose of ocrelizumab. This is given as two separate infusions at least 2 weeks apart for the first dose, and then subsequent doses as one infusion.
- Group 2: participants who weigh at least 40 kg, will be given a higher dose of ocrelizumab. This is given as two separate infusions at least 2 weeks apart for the first dose, and then subsequent doses as one infusion.

This is an open-label trial, which means everyone involved, including the participant and the clinical trial doctor, will know the clinical trial treatment the participant has been given is ocrelizumab.

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant. However, it may not be greater than the risks related to routine medical care or the natural progression of the health condition. People who would like to participate will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Risks associated with the clinical trial Participants may have side effects (an unwanted effect of a drug or medical treatment) from the ocrelizumab infusion used in this clinical trial. Side effects can be mild to severe, even life-threatening, and vary from person to person. Participants will be closely monitored during the clinical trial by their care team and safety assessments will be performed regularly.

Ocrelizumab

Participants will be told about the known side effects of ocrelizumab, and possible side effects based on human and laboratory studies or knowledge of similar drugs.

Ocrelizumab will be given by infusion. Participants will be told about any known side effects of infusions. To help with these side effects, participants will be given mandatory medications prior to their infusion.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial. Still, the information collected may help other people with similar medical conditions in the future.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov

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Trial-identifier: NCT04075266

Inclusion Criteria:

- Body weight >/= 25 kg
- Children and adolescents must have received all childhood required vaccinations
- Female participants of childbearing potential must agree to either remain completely abstinent or to use reliable means of contraception
- Diagnosis of relapsing-remitting multiple sclerosis (RRMS)
- Expanded Disability Status Scale (EDSS) at screening: 0-5.5, inclusive
- Neurologic stability for >/= 30 days prior to screening, and between screening and baseline
- Participants naive to prior disease-modifying therapy (DMT)
- Participants who have had at least 6 contiguous months of DMT within the past 1 year must have evidence of disease activity occurring after the full 6-month course of treatment, that is, at least one relapse or >/= 1 Gd-enhancing lesion(s) on a T1-weighted brain MRI

Exclusion Criteria:

- Known presence or suspicion of other neurologic disorders that may mimic MS, including, but not limited to, acute disseminated encephalomyelitis, neuromyelitis optica or neuromyelitis optica spectrum disorders and any neurologic, somatic, or metabolic condition that could interfere with brain function or normal cognitive or neurological development
- Patients that are aquaporin 4 positive and myelin oligodendrocyte glycoprotein (MOG) antibody positive are not eligible to participate in the study.
- In case of an ADEM-like appearance of the first MS attack, a second attack with clear MS-like features is required.
- Infection requiring hospitalization or treatment with IV anti-infective agents
- History or known presence of recurrent or chronic infection (e.g., HIV, syphilis, tuberculosis)
- Receipt of a live or live-attenuated vaccine within 6 weeks prior to treatment allocation
- History or laboratory evidence of coagulation disorders
- Peripheral venous access that precludes IV administration and venous blood sampling
- Inability to complete a magnetic resonance imaging (MRI) scan
- History of cancer, including solid tumors, hematologic malignancies, and carcinoma in situ
- History of a severe allergic or anaphylactic reaction to humanized or murine monoclonal antibody (mAbs) or known hypersensitivity to any component of ocrelizumab solution
- Previous treatment with B-cell-targeted therapies
- Percentage of CD4 < 30%
- Absolute Neutrophil Count < 1.5x1000/microliter
- Lymphocyte count below the lower limit of normal (LLN) for age- and sex-specific reference range