

Multiple Sclerosis (MS) Relapsing-Remitting Multiple Sclerosis (RRMS)

A clinical trial to compare the safety and effectiveness of ocrelizumab with fingolimod in children and young people with relapsing-remitting multiple sclerosis (RRMS)

A Study to Evaluate Safety and Efficacy of Ocrelizumab in Comparison With Fingolimod in Children and Adolescents With Relapsing-Remitting Multiple Sclerosis (RRMS)

Trial Status
Active, not recruiting

Trial Runs In
26 Countries

Trial Identifier
NCT05123703 2020-004128-41
2023-506516-40-00 WN42086

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:

A Phase III Multicenter, Randomized, Double-blind, Double-dummy Study to Evaluate Safety and Efficacy of Ocrelizumab in Comparison With Fingolimod in Children and Adolescents With Relapsing-Remitting Multiple Sclerosis

Trial Summary:

This double-blind, double-dummy study will evaluate the safety and efficacy of ocrelizumab compared with fingolimod in children and adolescents with RRMS aged between 10 and < 18 years over a flexible duration. The double-blind period will last until after the last participant randomized has completed 24 weeks.

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Phase 3
Phase

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Eligibility Criteria:

Gender
All

Age
#10 Years & # 17 Years

Healthy Volunteers
No

1. Why is the OPERETTA2 clinical trial needed?

Multiple sclerosis (MS) is a condition where the immune system attacks myelin – the protective layer around nerve fibres. This makes it difficult for the brain to send signals to the rest of the body. In children and young people, symptoms of MS include tiredness, pain, difficulties with language, memory and hand-eye coordination. Most experience the ‘relapsing-remitting’ form of the disease (RRMS), in which periods of attacks of old or new symptoms, known as ‘relapses’, are followed by times of fewer symptoms, known as ‘remission’.

Treatment of MS in children and young people includes treating relapses and symptoms. Some current medicines, such as fingolimod, are known as disease-modifying therapies – they can stop the disease from causing more damage to prevent relapses and symptoms from getting worse. Almost half of children and young people stop MS treatment because of side effects or because the treatment does not work well. New treatments for MS are needed.

For children and young people, ocrelizumab is an experimental disease-modifying therapy, which means it is not approved for treating MS in these age groups. Ocrelizumab is approved for the treatment of MS in adults. This clinical trial aims to compare the effects, good or bad of ocrelizumab versus fingolimod in children and young people with RRMS.

2. How does the OPERETTA2 clinical trial work?

This clinical trial is recruiting children and young people with RRMS. The trial has two parts – a ‘blinded- treatment’ part and an ‘open-label’ part.

In the blinded-treatment part, people who take part in this clinical trial (participants) will be given 1 of 2 clinical trial drugs, either ocrelizumab or fingolimod, and also a substance with no active ingredients (known as a ‘placebo’); it looks like the drugs being tested but does not contain any real medicine. Comparing results from the different groups helps the researchers know whether any changes seen result from the drugs or occur by chance. Treatment will be given for at least 6 months. Treatment may continue for up to 3 years depending on when they join the trial.

In the open-label part, participants who meet criteria and agree to continue treatment will be given ocrelizumab for at least 3 years.

The clinical trial doctor will see them regularly. These hospital visits will include checks to see how the participant responds to the treatment and any side effects they may have. After the last dose of clinical trial treatment, all participants will be seen every 3 months for about 1 year or longer if needed, to check their health. The total time of participation will be from 1 and half to more than 7 years depending on when they join the trial and if they continue the trial in the open-label part. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the OPERETTA2 clinical trial?

The main clinical trial endpoint (the main result measured in the trial to see if the drug has worked) is the number of relapses participants have during the blinded-treatment part.

The other clinical trial endpoints include:

- Changes detected by brain scans (magnetic resonance imaging, or MRI) in the blinded-treatment part
- Number and seriousness of side effects
- How the body breaks down and gets rid of ocrelizumab
- How treatment affects the immune system

4. Who can take part in this clinical trial?

People can take part in this trial if they are between 10–17 years old (inclusive) at the start of the trial, weigh at least 25kg and have been diagnosed with RRMS according to specific criteria.

People may not be able to take part in this trial if they have had certain treatments before, including fingolimod, or have certain medical conditions such as infections, another disease of the brain or spinal cord, heart, liver or lung problems, a history of cancer, or are pregnant or breastfeeding. People cannot take part if they are not able to have an MRI scan or give blood samples or have not had all recommended childhood vaccinations.

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

In the blinded-treatment part, everyone who joins this clinical trial will join 1 of 2 groups randomly (like flipping a coin) and be given either:

- Ocrelizumab, given as an infusion (into the vein) about every 6 months AND fingolimod placebo, given as a capsule (to be swallowed) once every day for at least 6 months and up to 3 years
- OR fingolimod, given as a capsule (to be swallowed) once every day for up to 3 years AND ocrelizumab placebo, given as an infusion (into the vein) about every 6 months

Participants will have an equal chance of being placed in either group. This is a double-blind part, which means that neither the participant nor the clinical trial doctor can choose or know the group the participant is in, until the part is over. This helps to prevent bias and expectations about what will happen. However, the participant's clinical trial doctor can find out which group the participant is in, if their safety is at risk.

After this part, participants who meet criteria and agree to continue treatment will join the open-label part, and can choose to be given:

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- Ocrelizumab, as an infusion (into the vein) about every 6 months for at least 3 years

Participants will be told which of the drugs they were given during the blinded-treatment part to help them decide if they want to continue in the open-label part of the trial. 'Open-label' means that everyone involved, including the participant and the clinical trial doctor, will know the participant has been given 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 drugs

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs 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; safety assessments will be performed regularly.

Participants will be told about the known side effects of ocrelizumab and fingolimod, and possible side effects based on human and laboratory studies or knowledge of similar drugs. Participants will be told about any known side effects of infusions into a vein (intravenous infusions) and swallowing capsules.

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](https://clinicaltrials.gov)

Trial-identifier: NCT05123703

Inclusion Criteria:

- Body weight # 25 kilograms (kg)
- Diagnosis of RRMS in accordance with the International Pediatric Multiple Sclerosis Study Group (IPMSSG) criteria for pediatric Multiple Sclerosis (MS), Version 2012, or McDonald criteria 2017

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- Expanded Disability Status Scale (EDSS) at screening: 0-5.5, inclusive
- For all countries except Germany, at least one MS relapse during the previous year or two MS relapses in the previous 2 years or evidence of at least one Gd enhancing lesion on MRI within 6 months

Inclusion Criteria for Optional OLE Period:

- Participants in Group A (ocrelizumab in the double-blind period [DBP]) and Group B (fingolimod in the DBP) who, in the opinion of the investigator, may benefit from switching to ocrelizumab and who have completed the DBP with study treatment (ocrelizumab/fingolimod), may participate in the OLE period

Exclusion Criteria:

- Known presence or suspicion of other neurologic disorders that may mimic MS
- Significant uncontrolled somatic diseases, known active infection or any other significant condition that may preclude participant from participating in the study
- Participants with severe cardiac disease or significant findings on the screening Electrocardiograph (ECG)

Exclusion Criteria for Optional OLE Period:

- Participants who have discontinued the study during the DBP