ForPatients
by Roche

Multiple Sclerosis (MS)

A clinical trial to look at how safe different doses of RO7121932 are in people with multiple sclerosis and how the body processes RO7121932

A Study to Investigate the Safety, Tolerability, and Processing by the Body of Intravenous RO7121932 in Participants With Multiple Sclerosis

Trial Status	Trial Runs In	Trial Identifier
Recruiting	10 Countries	NCT05704361 2020-004122-33 BP42230

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

The primary purpose of the study is to evaluate the safety and tolerability of single ascending intravenous (IV) doses of RO7121932 in participants with multiple sclerosis (MS)

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT05704361 2020-004122-33 BP42230
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years & <= 65 Years	No

1. Why is the B-Shuttle clinical trial needed?

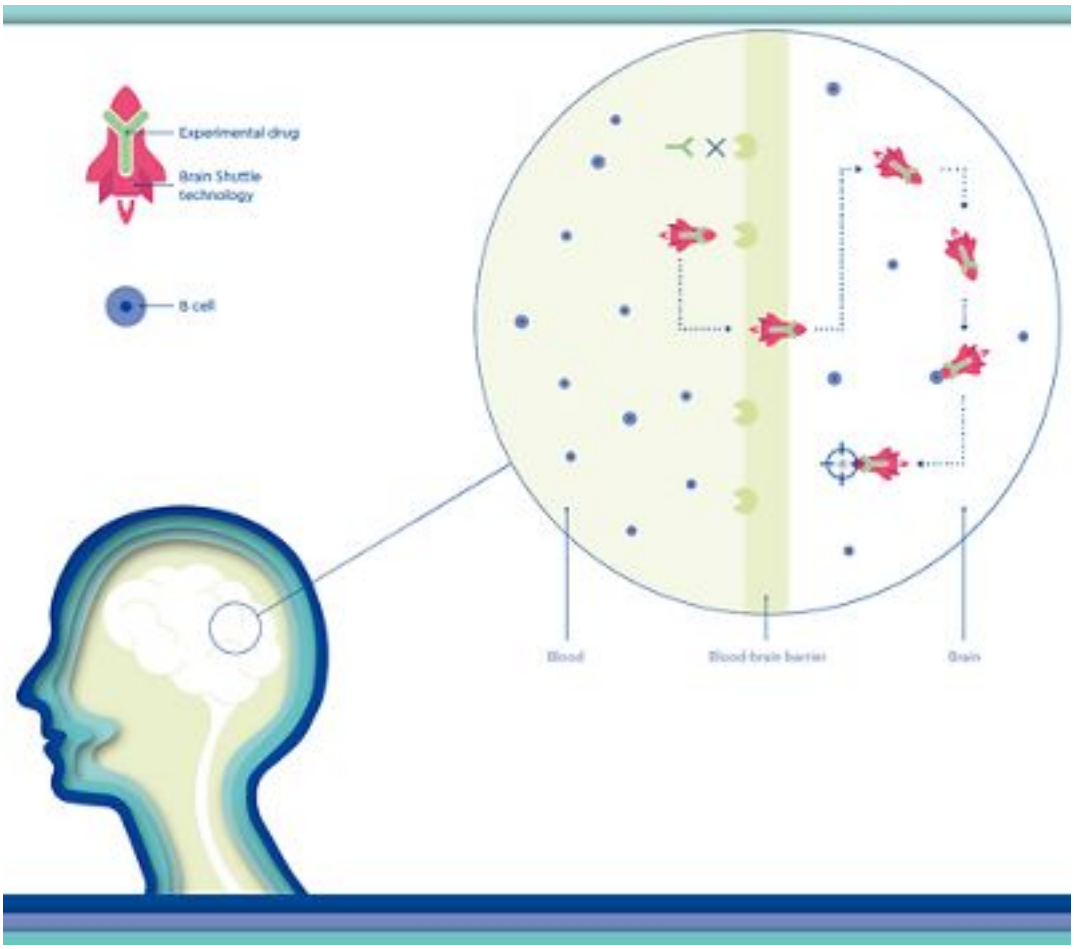
Multiple sclerosis (MS) is a condition where the immune system attacks myelin, the protective layer around nerve fibres. This makes it difficult for the brain to send signals to the rest of the body. Common symptoms include pain, tiredness, vision problems and problems with walking or balance. Most people experience the ‘relapsing-remitting; form of the disease, in which periods of attacks of old or new symptoms, known as ‘relapses’, are followed by times of fewer symptoms, known as “remission”. As opposed to the relapsing-remitting type of MS, people with ‘progressive’ MS have symptoms and disabilities that stay stable for a long time or worsen over time. It is thought that increasing disability in progressive MS is due to nerve damage in the brain.

Treatments for MS include:

- Treatment during relapses (usually with steroids)
- Treatment of symptoms (such as muscle stiffness/spasms, pain, tiredness and depression)
- The use of disease-modifying therapies (DMTs) to prevent MS relapses and maintain body functions. ‘Relapsing-remitting MS’ may develop into ‘secondary progressive MS’, which is characterised by slowly increasing disability with or without relapses.

Immune cells that usually protect the body from foreign (or harmful) substances, including bacteria or viruses, can attack nerve cells in people with MS. Treatment with DMTs can reduce disease activity. But a protective barrier around the brain (called the ‘blood-brain barrier’) can make it difficult for medicines like DMTs to pass through and prevent damage to the nerves. Currently, DMTs do not work very well at stopping disability caused by immune cells in the brain both in relapsing and progressive forms of the disease.

RO7121932 is the clinical trial treatment being tested in this trial – it is an experimental drug (health authorities have not approved it for treating MS) with a ‘brain shuttle technology’ that allows the drug to pass through the blood-brain barrier. Researchers hope that RO7121932 will lower the number of a type of immune cell called ‘B-cells’ in the brain to prevent disability progression in MS. This clinical trial aims to test the safety of RO7121932 at different doses in people living with MS, to understand how well it is tolerated, to measure how the body absorbs, distributes, and gets rid of it and find out what effects, good or bad, RO7121932 has.



2. How does the B-Shuttle clinical trial work?

This clinical trial is recruiting people with relapsing as well as primary and secondary progressive forms of MS. People can take part if they are not currently treated with DMTs and they did not have very recent MS activity (assessed via relapses and magnetic resonance imaging [MRI] scans).

People who take part in this clinical trial (participants) will be given a single dose of the clinical trial treatment RO7121932. They will need to stay in the hospital for up to two nights after being given RO7121932 on Day 1. The clinical trial doctor will see them on Days 1–3, 5, 8, 11, 15, then weekly for 2 weeks, then once a month for 3 months, with a final follow-up visit at 6 months. These hospital visits will include medical checks to see how the participant responds to the treatment and any side effects they may have – some visits/tests may be done by a mobile nurse at the participants' home if they agree to it. Participants who still have low blood B-cell counts at the follow-up visit will be asked to attend the hospital for monthly blood tests until their B-cell levels are back to normal values. Total time of participation in the clinical trial will be about 8 months. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the B-Shuttle clinical trial?

The main clinical trial endpoint is the main result measured in the trial. In this clinical trial, the main endpoint is the number and seriousness of any side effects during treatment and the 6-month follow-up period.

The other clinical trial endpoints include:

- How the body breaks down, processes and gets rid of RO7121932
- How RO7121932 affects the immune system

4. Who can take part in this clinical trial?

People living with MS can take part in this trial if they are 18–65 years of age (inclusive) and are not being treated with DMTs (people can continue having physiotherapy or taking any treatments for MS symptoms that they have already started).

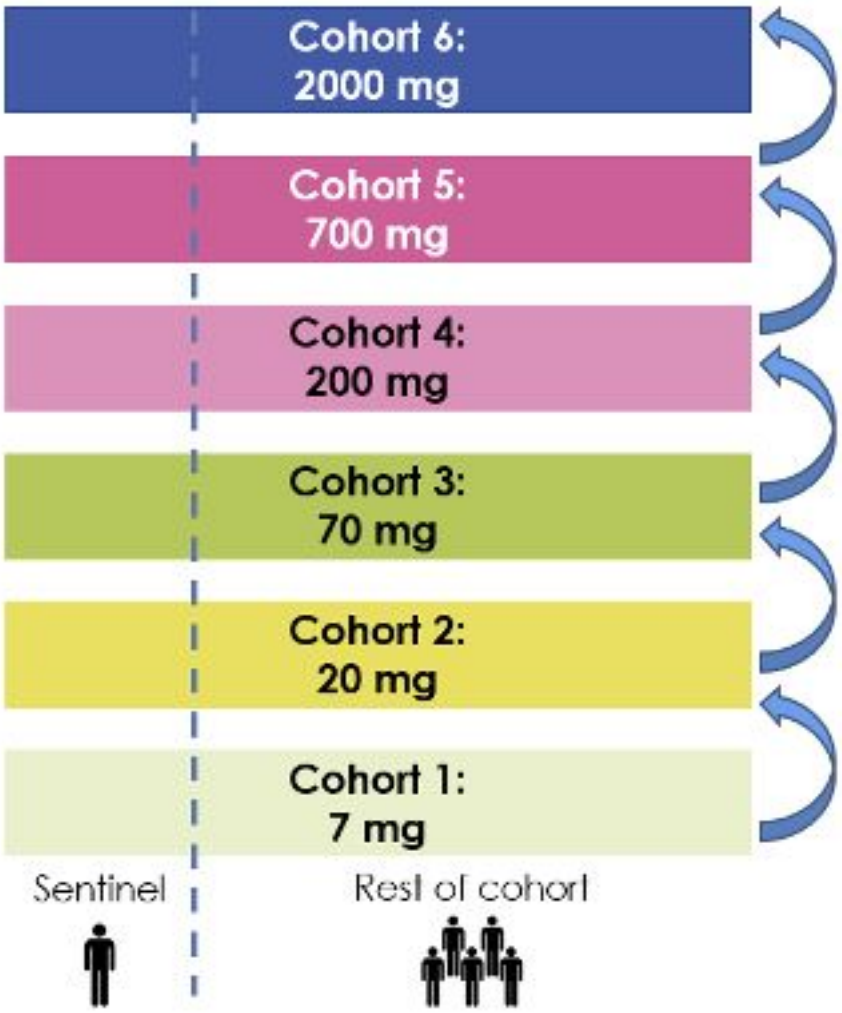
People can take part if they have had no recent MS activity – which means they have not had a relapse within 3 months before the start of the trial, have had only one relapse within the past year or have few new or enlarging lesions in the brain on a recent MRI scan. People may not be able to take part in this trial if they cannot walk 5 metres or more with or without aid from devices, have recently received certain treatments such as B-cell therapies, have certain medical conditions other than MS including those affecting the brain or spinal cord, infections, cancer within the last 10 years, or if they are pregnant or breastfeeding, or are planning to become pregnant during the trial.

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

Everyone who joins this clinical trial will be given:

- **RO7121932**, given once, as an infusion (into the vein)

If participants have a relapse or their MS becomes active again as shown on MRI scans, they may be offered approved immunotherapy treatment if the study doctor believes this will benefit them. This is an open-label trial, which means that everyone involved, including the participant and the clinical trial doctor, will know the clinical trial treatment the participant has been given.



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 MS. 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 drug
Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drug 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.

RO7121932
RO7121932 has not yet been tested in humans. For this reason, this experimental drug's side effects are not yet known. Participants will be told about the possible side effects based on laboratory studies or knowledge of similar drugs. RO7121932 will be given as an infusion into a vein (intravenous infusion). Participants will be told about any known side effects of intravenous 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.