ForPatients
by Roche

Systemic Lupus Erythematosus

A clinical trial to look at how safe different doses of RO7507062 are in people with systemic lupus erythematosus and how the body processes this drug

A First-in-Human Study to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of RO7507062 in Participants With Systemic Lupus Erythematosus

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	13 Countries	NCT05835986 2022-502632-39-00 BP44315

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 purpose of this study is to investigate the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of RO7507062 in participants with systemic lupus erythematosus (SLE). The study will have 2 parts: Part 1 is a single ascending dose-finding (SAD) part and Part 2 is a dose escalation with fractionated dosing part.

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

NCT05835986 2022-502632-39-00 BP44315
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years & <= 70 Years	No

1. Why is the BP44315 clinical trial needed?

Systemic lupus erythematosus (SLE) is an autoimmune disease, which means the immune system attacks the body by mistake. This causes damage and inflammation and can affect the joints, skin, brain, lungs, kidneys and blood vessels. In SLE, a type of cell of the immune system called B cells produce antibodies (blood proteins normally made to help defend the body against infection) that attack the body (also known as ‘autoantibodies’). SLE is a ‘relapsing remitting’ disease. Symptoms flare up when SLE is in

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an ‘active’ state when more autoantibodies may be produced (also known as ‘relapsing’). Symptoms reduce when SLE is not active (known as ‘remitting’). Standard treatment aims to reduce inflammation and suppress the immune system, and includes steroids, hydroxychloroquine and immunosuppressants such as mycophenolate mofetil (MMF), azathioprine, methotrexate or cyclophosphamide. Antibody therapies called anifrolumab and belimumab have been approved for people with SLE who are taking standard treatment.

Despite treatments being available, people with SLE are more likely to have additional health conditions, such as kidney involvement, one of the most common and serious organ complications of the disease. Some people have unacceptable side effects to treatment, or treatment may stop working (known as ‘refractory’ disease). New treatments for SLE are needed.

RO7507062 is a drug designed to remove B-cells in people with SLE. RO7507062 is an experimental drug - i.e. health authorities have not approved it as a treatment for SLE. This clinical trial aims to test different doses of RO7507062 to determine how safe the treatment is, and to understand how the body processes RO7507062.

2. How does the BP44315 clinical trial work?

This clinical trial is recruiting people living with SLE. People can take part if they have SLE autoantibodies and ‘active’ SLE. This trial is divided into two parts, Part 1 and Part 2. People (participants) who join the first part of this clinical trial (Part 1) will be given a single dose of the trial drug RO7507062 and those who join the second part of this trial (Part 2) will be given maximal 3 doses RO7507062 in the first month. Participants will stay in the hospital and have assessments six times on the day that RO7507062 is given, then daily for at least 3 days. After this, participants can leave the hospital and will either be seen or telephoned by the clinical trial doctor regularly during the first month, then monthly for 5 months, then every 3 months until about 1 year after the first RO7507062 dose. These checks are to see how participants respond to the treatment, if there are changes in B cell levels in the blood and to monitor for any side effects the participants may experience; some of the later checks may be done by telephone. The total time in the clinical trial is expected to be just over 1 year (13 months). However, if the B cell level in the blood is still low at the 1-year visit, the participant will be checked every 6 months until their B cell level becomes normal. Participants can stop trial treatment and leave the trial at any time.

3. What are the main endpoints of the BP44315 clinical trial?

The main clinical trial endpoints (the main results measured in the trial to see if the drug has worked) are, with different doses of RO7507062:

- the number and seriousness of any side effects
- the type of side effects, and

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- how often side effects occur.

Other clinical trial endpoints include how the body processes RO7507062.

4. Who can take part in this clinical trial?

People can take part in this trial if they are between 18 and 70 years old and have been diagnosed with SLE for at least 6 months.

People may not be able to take part in this trial if they have:

- Nerve or brain conditions (such as meningitis) or other severe conditions due to SLE
- Previously received certain treatments, including certain immunosuppressants or B-cell antibody therapies within 6 months of or during the screening period
- Certain other medical conditions such as other autoimmune diseases, infections, chronic obstructive pulmonary disease, cancer within the last 5 years, pregnancy or breastfeeding, or people planning to conceive during or shortly after the trial (within 3 months after the final dose of RO7507062).

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

Participants will be given maximal of 3 doses of **RO7507062** as an injection under the skin (subcutaneous injection) of the stomach area – groups of people will be given different doses of **RO7507062** so that doctors can understand more about the safest and most effective dose to give. 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. If a participant experiences a potential side effect called ‘cytokine release syndrome’ (when the body’s immune cells are activated and release large amounts of inflammatory substances throughout the body), they may receive another medicine called tocilizumab.

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 are 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 medical treatment) from the drugs used in this clinical trial. Side

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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. **RO7507062** is being tested in humans. For this reason, this drug's side effects are not known yet. **RO7507062** will be given as a subcutaneous injection and participants will be told about any known side effects of subcutaneous injections. Risks possibly associated with RO7507062 are described in the informed consent document. Additionally, participants will be told about the known side effects of tocilizumab and possible side effects based on human and laboratory studies or knowledge of similar drugs. Tocilizumab (if required) 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.

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