POSTERITY

Patient brochure

Information about the POSTERITY study

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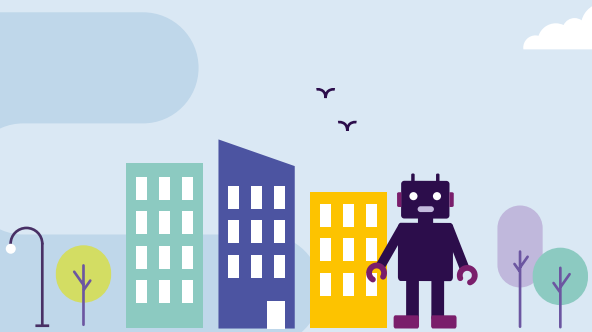


Adolescent lupus nephritis? Let's tackle it together

Lupus nephritis (LN) is an autoimmune disease which leads to inflammation of the kidneys. It's caused by systemic lupus erythematosus (SLE) and occurs more frequently in younger patients compared with adults who develop lupus. It's a serious condition and yet limited treatment options exist. Therefore, developing a new effective treatment option for LN is really important.

That's why we're conducting the POSTERITY study – a clinical study that will see how safe and effective a study drug is in combination with current standard treatment for LN. The information obtained from this study may help children and adolescents below age 18 with LN in the future.

We're looking for 30 people to join who (among other things):

- Are age 12 to less than 18 years old
- Are diagnosed with LN

This brochure will tell you about clinical research in general. It will also explain why the POSTERITY study is being conducted and describe what taking part will involve. If you have any questions or would like to learn more, please don't hesitate to contact us using the details on the last page.

What is a clinical study?

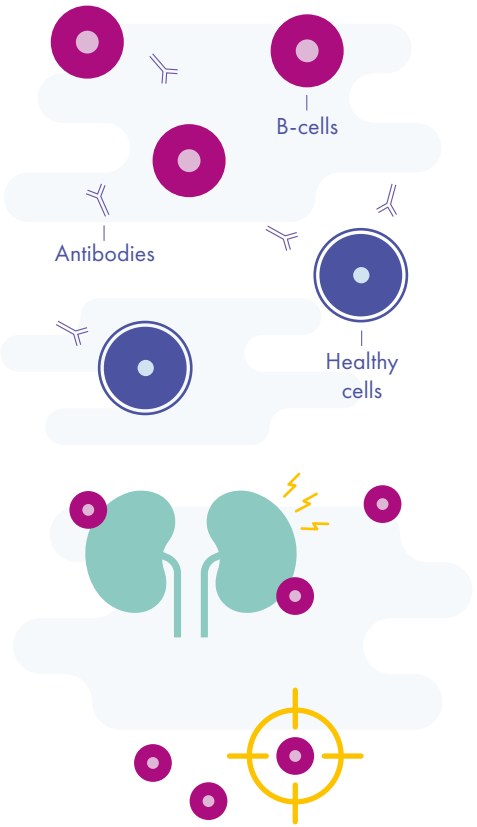
Clinical studies (also known as 'clinical trials') are carefully controlled scientific investigations that help us find:

- Potential new treatments
- New forms of treatments already being used
- New uses for treatments already being used

Thousands of people all around the world take part in clinical studies every year. In fact, every drug that you've ever taken will have been researched in clinical studies that were only possible because of their participants.

Each study follows a plan (known as a 'protocol') that must be approved against a strict set of rules. A clinical study can only take place once it's been approved. This is to protect the safety and privacy of every study participant.

About the study drug being tested in POSTERITY



The immune system is a complex network of cells that work together to protect the body from harmful substances such as 'bad' bacteria and viruses

B-cells are one part of the immune system. They produce antibodies to fight these harmful substances

However, in conditions known as 'autoimmune diseases,' such as lupus, the body's B-cells 'overreact' and attack healthy cells instead

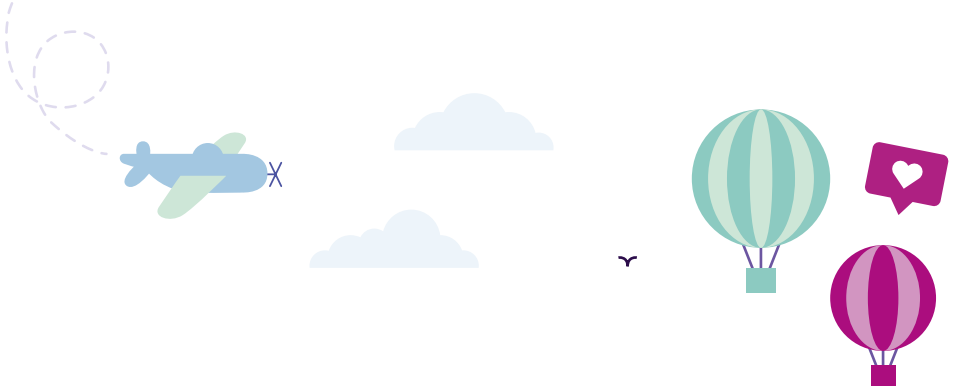
In patients with LN, the B-cells have attacked and inflamed the kidneys

The study drug that is being tested in the POSTERITY study is thought to work by targeting and destroying these overreactive B-cells

In a previous study of this study drug, it was found to improve kidney health in adults with LN. The purpose of this study is to assess the safety and efficacy of the study drug in adolescent participants with proliferative LN to address a significant unmet medical need in this patient population.

What will this study involve?

You will be asked to visit your study doctor and remain in the study for at least 2 years. However, you may be asked to visit your study doctor for longer than this. This could be approximately 3.5 years or longer, if your study doctor tells you this is needed. The study is divided into four periods, as shown below:



Screening period (Up to 4 weeks)

We'll carry out some tests to make sure that you're eligible for the study.

Double-blind treatment period* (Approximately 76 weeks)

You'll be randomly assigned (like the toss of a coin) to receive either:

Five infusions of the study drug (2 in 3 chance)

or

Five infusions of a placebo (1 in 3 chance)

This means that you are two times more likely to receive the study drug than a placebo. After the 76 week double-blind treatment period, the study doctor will review how you've responded to your assigned study treatment. Depending on this review, you'll either continue to the **treatment extension period**, or enter the **safety follow-up period**.

You'll receive your usual background tablets of corticosteroid (prednisone or a similar drug) and mycophenolate mofetil (MMF) for your lupus nephritis.

About 30-60 minutes before you're given your study treatment, you'll receive premedication. This will include a medicine called a steroid, a painkiller (like paracetamol) and an antihistamine (anti-allergy) tablet that helps reduce any side effects you may have.

Treatment extension period* (Approximately 76 weeks)

Depending on the review at the end of your double-blind treatment period, you'll either:

Continue to receive the same study treatment (study drug or placebo) but you won't know which one. You'll receive three infusions of your study treatment during this 76 week period.

or

You'll receive the study drug 'open-label' (you'll know you're receiving the study drug and not the placebo). You'll receive five infusions of the study drug during this 76 week period.

You'll receive your usual background tablets of corticosteroid and MMF. Your study doctor may adjust your dose if needed.

In addition, you'll continue to receive premedication before your study treatment.

Safety follow-up period (At least 12 months after last infusion)

We'll continue to monitor your health and condition once every six months. These visits will last for as long as is necessary (for a minimum of 12 months after your last study treatment infusion). You may continue to receive the standard treatment for LN (corticosteroids and MMF) during the safety follow-up period, at your study doctor's discretion.

*Please see the next page for a definition of 'placebo', 'blinded' and 'open-label' treatment.

What is a placebo?

A placebo looks just like the study drug and is given the same way. However, it contains no active medicine and is often called a 'dummy-drug.'

What does 'blinded' mean?

Blinded means that you don't know what you're taking. Both the initial treatment period and (for some participants) the treatment extension period in this study are 'double-blind'. This means that neither you, your caregiver, nor the study team will know whether you've been assigned the study drug or the placebo. We do this so that we can be sure that any differences seen are due to the study drug and not some other factor. However, after the 76 week review by your study doctor, you may be offered the study drug 'open-label' during the treatment extension period. Open-label means you'll know that you're taking the study drug.

How is the study treatment given?

Both the study drug and the placebo will be given as an intravenous (IV) infusion (a 'drip' into the vein). This will take between four and five hours each time.

How will my health be checked?

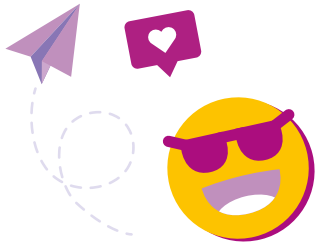
During the study, you'll have 11 visits through Week 76 (over a period of approximately 18 months). Some study clinics may send a mobile nurse to your home, or a location near your home, in place of certain visits. This means you won't have to visit the clinic as often. Please ask your study team if mobile nursing is an option for you. Most of your visits are for the study team to check your general health and see how you're responding to your study treatment. If you opt to enter the extension period, there will be up to 9 more visits over another 18 month period. Safety follow-up visits will occur every 6 months for at least 12 months after the last infusion of study drug. Health checks will vary between visits, but may include:

Blood tests

Urine tests

Physical exams

On average, these clinic visits will last for one to two hours (although your study treatment visits may last up to five or six hours).



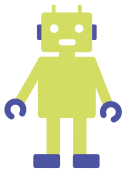
Can my caregiver stay with me during study clinic visits?

Yes. Your caregiver must accompany you to study clinic visits and will be able to stay with you during health assessments and study procedures where possible. **Please remember, some study clinics may offer participants a mobile nursing service in place of certain visits.**

Do I have to take part?

No. As a volunteer, you can change your mind and leave the study at any time without any impact on your regular healthcare. We recommend talking things through with your family before you make a decision.

Notes



How can I learn more?

If you have any questions or would like to find out more, please contact the study team. They'll be happy to help and can answer any of your or your family's questions related to this study.

Clinical site study team contact details:

[CONTACT DETAILS]