ARROYO

Patient Information

This brochure contains information about the ARROYO Study for people with chronic spontaneous urticaria (persistent hives). This information should help you decide whether you or someone you know may want to take part in the study.

What is a clinical research study?

A clinical research study is a medical study that helps to answer important questions about a study drug, such as:

- Does it work?
- What amount, or dose, may work best?
- How often should it be given?
- How safe is it?
- Are there side effects?

All medications must be tested in clinical research studies before they can be approved to prescribe to patients. Without people taking part in these studies, we would have no new medications.

Deciding to take part in a clinical research study is your decision. If you have any questions, you can contact the study team using the information provided in this brochure.

About the ARROYO Study

The ARROYO Study is being carried out to learn more about whether the study drug works, and how safe it is for people with chronic spontaneous urticaria (CSU), a form of persistent hives. This type of hives is different from hives that occur for a short time (acute hives), and hives triggered by the heat or cold (inducible hives) – neither of these is included in this study.

Why is the ARROYO Study important?

The study is being done because treatment options for CSU are limited for people with CSU whose symptoms do not respond well enough to antihistamines. The study drug has been approved in more than 50 countries worldwide for treating severe asthma, and will now be studied in CSU.

What will the ARROYO Study involve?

If you take part, you will be in the study for up to 1 year and 3 months. You will need to:

- attend study center visits every 4 weeks
- receive an injection of study drug or placebo (an injection without the active ingredient) every 4 weeks
- continue taking regular doses of antihistamine
- complete a daily diary of your symptoms and which medications you took.

The study has 4 periods.

Screening period of up to 4 weeks

Visit the study center to see if the study is right for you and whether you want to take part.

First study dosing period of 24 weeks – study drug or placebo (1 in 4 patients will get placebo)

Visit the study center 6 times (once every 4 weeks) for study assessments.

Second study dosing period of 28 weeks – study drug

Visit the study center 8 times (once every 4 weeks) for study assessments.

Follow-up period of 8 weeks

Visit the study center once for study assessments after you have received the last dose of study drug.

In times of a pandemic or national emergency, there may be disruptions to the study, and you may not be able to visit the study center. If this happens, you may have a healthcare professional visit you at home, or a telemedicine visit by phone or video.

Who can take part?

You or someone you care for may be able to take part if the following apply:

- aged 18 years or older
- diagnosed with CSU
- presence of itching and wheals (hives) for at least 6 weeks despite taking an antihistamine.

What else do I need to consider?

- The study team can explain the possible benefits and risks of the study to you.
- You do not have to take part in the study if you don't want to.
- If you choose to take part in the study, you can stop participating at any time.
- You will not be paid to take part in this study, but you may be reimbursed for reasonable travel costs during your participation.
- All study medications and study-related tests will be provided at no cost to you.
- A team of doctors and nurses will monitor your health carefully during the study.

How do I get more information?

To find out more, please contact the study team using the information provided here. Study participation is voluntary. By contacting us, you are under no obligation to take part in the study.