

Join our childhood asthma research study

Information for parents and caregivers

We are researching into childhood asthma

We are conducting a clinical research study (FSS-AS-30003) to see if an investigational medication can help get the most suitable dosing levels for children who have persistent asthma.

This brochure will tell you more about this clinical research study and what taking part involves. If you have any questions, please do not hesitate to contact a member of the study team.



What is a clinical research study?

Every year, hundreds of thousands of people around the world take part in clinical research studies.

The results help shape the future of medicine. By asking specific questions, such research studies help find and test:

- New ways to diagnose illnesses
- New medications and devices
- New uses for existing medications and devices

Clinical research studies must follow a 'protocol', which is a plan that details exactly what will happen during the study and how your child's health will be monitored. Each one is reviewed by independent institutional review boards and ethics committees before it can begin.

Why are we doing this clinical research study?

This research study will see if certain doses of an investigational medication are an effective way to control childhood asthma.

We're looking to recruit about 600 children worldwide, who:

- Are 4–11 years old
- Were diagnosed with asthma at least 3 months ago
- Have been diagnosed with persistent asthma
- Haven't had any asthma attacks for at least 30 days
- Are otherwise healthy

What happens during the clinical research study?

The FSS-AS-30003 clinical research study lasts between 15 to 17 weeks.

Your child will be randomly (by chance) assigned to one of four groups and will either receive an investigational medication or placebo. It is important we use a placebo as a control (a 'dummy' drug with no active ingredient). This allows us to check if other factors apart from the active ingredient in the investigational medication have influenced our

research results. There is a one in four chance of your child receiving a placebo; otherwise, they will be given an investigational medication. You won't know which group your child has been assigned to, and neither will the study team.

Your child will need to take one breath of the investigational medication or placebo through an inhaler, twice daily, every 12 hours. A second inhaler will also be provided to replace your child's current rescue medication.

How will my child's health be monitored?

Your child will need to come to the clinic up to eight times over 15 to 17 weeks so that we can check their health. These visits vary from visit to visit, but will include:

- Physical examinations
- Blood pressure, pulse rate, heart monitoring and lung examinations
- Mouth and throat examinations
- Lung function tests
- Questionnaires about their asthma
- A urine pregnancy test for girls who have had their first period, as your child cannot be in the study if she is pregnant

We'll also ask you to help your child keep a daily record of their asthma using a handheld electronic device. This device measures lung function and is also used as a diary. We will also check that your child is using their inhalers correctly.

Is there anything else I should know?

Before your child receives the study medication you'll need to read and sign an informed consent form. Your child will be given an informed assent form, a simpler version to sign. This shows they understand what is involved in the study and agree to take part.

Taking part in a clinical research study is entirely voluntary. Your child can leave the study at any time (even if they have started taking the study medication) and their future healthcare will not be affected.

Participants do not need to have insurance to take part and all study-related medications, tests and assessments will be given to participants at no cost. Reimbursement for time, travel and other study-related expenses may be available.

Thank you for your interest

To learn more about this research study, please contact the study team using the details below. We are happy to answer your questions and also to schedule a face-to-face meeting. We look forward to hearing from you.

Thanks for your time!

Research study team contact details:

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