

? Are there other study commitments?

During the main study period, all participants (with the help of a parent/caregiver for those under 12 years of age) will undertake daily at-home monitoring of lung health and asthma symptoms.

🙋 Is this study voluntary?

Yes. Participation is your choice. If you/your child decide not to take part, this will not affect your/your child's usual healthcare.

If you/your child decide to take part, you'll be helping researchers and doctors understand severe eosinophilic asthma better, and playing an important role in ongoing efforts to improve healthcare for people with this condition.



📞 How do I find out more?

If you would like to find out more about the **DOMINICA Study** and who can join, please contact:

Name: _____

Study center: _____

Address: _____

Telephone: _____

Email: _____

Contacting us does not mean that you/your child must join the study or that you/your child will be able to participate. The study team can explain more about the **DOMINICA Study** and what taking part will mean for you/your child.

Thank you for your interest in the DOMINICA Study!



Be a Part of Our Air Crew!



Stock photo. Posing by model.

Study Information Brochure





What are clinical research studies?

Clinical research studies are necessary for developing new drugs or treatments. Sometimes a drug that is already approved by health authorities may be investigated in further clinical research studies to find out if it is safe and effective in other ways, such as treating other symptoms of an illness or different age groups.

Clinical research studies are carried out according to strict guidelines – these make sure that the **safety and well-being** of all people taking part are the **top priorities at all times**.



What is the DOMINICA Study?

A small number of people with asthma have a 'severe eosinophilic' form. 'Severe' means that the asthma is not controlled despite use of available treatments. 'Eosinophilic' means that there is inflammation in the airways caused by the body's own immune system.

The drug, **benralizumab** (marketed as Fasenra®), is approved by health authorities in more than 60 countries worldwide for people with severe eosinophilic asthma to use in addition to their asthma prevention medication (in three countries, it is approved for use by people as young as 12 years). The **DOMINICA Study** will evaluate whether benralizumab has an effect on asthma episodes, and if it can improve symptoms of this condition and quality of life – in young children and teenagers – age groups for whom the drug is not yet approved.

This brochure is for teenagers and parents/caregivers of children who may be interested in joining the study.



Who can take part?

We are looking for people who:

- Are **6 to 17 years of age**.
- Have had **severe asthma** for **at least 6 months**.
- Have had **asthma episodes** over the last year that **required steroid medication** or **hospital treatment**.
- Are already **using an inhaled steroid plus at least 1 additional asthma medication**.

There are other criteria that you/your child will need to meet to join the study, which the study team will discuss with you.

Who will take part in the DOMINICA Study?

At least **200 children and teenagers** at study centers around the world are expected to take part.



Which study drug will I/my child receive?

In the main part of the study, there is an **equal chance** (50:50) of receiving **benralizumab** or **placebo**. Placebo looks exactly like benralizumab, but contains **no active medication**. You cannot choose which of benralizumab or placebo you/your child receives.

In an **extension period** to the main study, **all participants will receive benralizumab**.

Both benralizumab and placebo will be given as an injection, just under the skin, by a member of the study team at study visits. In the study extension, there may be an opportunity to receive the injections at a location of your choice from a study-specific healthcare professional, or for older teenage participants or caregivers to be trained in how to administer the injection.

There will be no charge for any study-related treatment or care



What happens during the study?

The study is made up of the following parts:

Screening – around 2 months

- To check if you/your child can take part in the study (1 study center visit).

Main study – at least 16 weeks

- Scheduled study visits (between 4 to 8 weeks apart).
- Receive benralizumab or placebo.

Extension – 48 weeks (ages 12 to 17 years) OR 2 years (ages 6 to 11 years)

- Scheduled study visits (between 4 to 8 weeks apart).
- Receive benralizumab.

Follow-up – about 8 weeks after the final dose of study drug

- Have 1 final study center visit.



What happens at study visits?

Your/your child's health and response to their assigned study drug will be assessed in various ways, including the following:

- Tests of lung health.
- Questions about your/your child's asthma symptoms and quality of life.
- Tests to measure the electrical activity of the heart.
- Collection of blood and urine samples.

Study visits will usually be at the study center, and take **between 1 and 3 hours**. Some visits could be split over 3 days – your study doctor will let you know if this is possible at your location. During the extension period, there may be an option to arrange for some of the study visits to take place in your own home.