ARIA ASTHMA RESEARCH IN ADOLESCENTS

Asthma won't hold me back

The ARIA clinical research study for teenagers (12–17 years) with asthma

Learn more about the
ARIA clinical research study

This guide provides an overview of the ARIA study, who can participate, and what to expect. If you are considering having your (or other relation) teenager (12 to 17 years, inclusive) participate, you will receive an informed consent form (ICF) with more detailed information before they join. Participation is entirely voluntary, and your (or other relation) teenager is not obligated to join if you enquire or request more information. **Please scan the QR code to visit the study website for additional information**.

Please scan the QR code to visit the study website for additional information: teenasthmastudy.com

About the ARIA clinical research study

One of the current medicines licensed for the treatment of asthma is a single puff, once daily, dry powder inhaler containing two medicines. This double-therapy inhaler is licensed for the treatment of asthma in patients aged 5 years and older.

The ARIA study is evaluating a similar single puff, once daily, dry powder investigational inhaler containing **three medicines** for the treatment of asthma in teenagers aged 12 to 17 years. This triple therapy inhaler is already licensed to treat asthma in adults aged 18 and older in the country where you live. The ARIA study aims to see if this investigational triple therapy inhaler can also be effective for teenagers aged 12 to 17 with uncontrolled asthma.

To perform this evaluation, the investigational triple therapy inhaler will be compared to the double therapy inhaler in teenagers (12–17 years) over 24 weeks. All participants will receive asthma treatment and quick relief "rescue" treatment to use as needed for asthma symptoms throughout the study.

In the ARIA study, your (or other relation) teenager's safety and well-being are our top priorities. We'll closely monitor their health throughout the study to ensure their safety. Our team is dedicated to supporting both of you and addressing any queries or concerns you may have.

About the investigational triple therapy inhaler

The safety of the triple therapy inhaler has already been studied in 2,436 adults whose asthma wasn't well controlled with their current medicine. The triple therapy inhaler has been compared with an already licensed double therapy inhaler for asthma treatment in adults.

Participants taking the triple therapy inhaler showed **significantly improved lung function** compared to those taking the double therapy inhaler. The safety profile of the two inhalers was similar.

Based on these clinical study results, the triple therapy inhaler is now **licensed as a prescription medicine** for treating asthma in adults in several countries, including the country where you live. This medicine is the first approved single puff, once-daily, triple therapy inhaler for adults with asthma.

The ARIA study is evaluating whether this investigational triple therapy inhaler can also be beneficial for **teenagers aged 12 to 17**.

Who can take part?

To join the study, participants must:

- Be aged between **12 and 17 years old**
- Have **uncontrolled asthma**
- Have been on **stable maintenance therapy** for at least 6 weeks

This is not a complete list of criteria; potential participants will need to answer some additional health questions and undergo some medical tests to confirm that they can join the study.

What can be expected during the study?

Participants will be in this study for about 7 months and will have at least 6 study visits during this time. These visits may all take place at the study clinic or, if permitted and approved, some visits may be over the phone, or remotely from home. Involvement in the study is designed to have as minimal an impact as possible on home and school life.

For those who choose to participate in the study, a full visit schedule with all the details needed for each study appointment will be provided.

You will also receive communication and information materials to provide to your (or other relation) teenager's school to ensure they are informed and can provide support and adjustments as necessary. This is intended to help minimise disruptions to their school routine and allow them to continue participating in academic and social activities during the study.

How will the study medicines be given?

All participants will start by taking the already licensed **double therapy inhaler once daily for 4 weeks**.

After this period, participants will be **randomly assigned** to either continue with the double therapy inhaler or switch to the investigational triple therapy inhaler, both taken once daily for the next 24 weeks.

Throughout the study, neither participants, caregivers, nor the study team will know which inhaler has been assigned. **This information can be accessed if necessary** for safety reasons.

Participants will also receive a **quick relief** "rescue" **medicine inhaler** (albuterol/salbutamol) to use as needed for asthma symptoms during the study.

How will participants' health be monitored during this study?

During the study, participants' health will be closely monitored through regular visits to the study site. These visits may include various tests and assessments, such as:

Physical examinations

Vital signs measurements (blood pressure and heart rate)

Breathing assessments

Questionnaires

Blood tests

Urine tests

Not all of these activities will occur at every visit.

Each visit may take approximately 2 hours and is designed to be convenient and efficient for participants and their caregivers. We aim to minimise disruption to participants' daily lives while ensuring thorough care for participants' health.

What are my responsibilities as a caregiver in this study?

- Talk to the study doctor or study staff about the study
- Personally accompany the participant to all study visits
- Provide information about the participant to the study doctor and staff
- Tell the study doctor or study staff if either you or the participant wants to stop being in the study
- Help the participant follow study instructions
- Tell the study doctor or study staff about any changes to the participant's current medication use (including over-the-counter medications, vitamins, and supplements)

Will there be any costs for participating?

The study medicine, study-related procedures, and study visits will be free to participants.

What are the benefits and risks of being in this study?

Participating in a clinical study helps improve medical knowledge, providing information about the benefits and possible risks of potential new medicines. Both licensed medicines and investigational medicines can cause side effects, which the study doctor will explain to participants and their caregivers before joining the study.

In the ARIA study, the safety and well-being of participants are top priorities. A dedicated team of healthcare professionals will closely monitor participants throughout the study with regular check-ups and assessments. This ensures any potential side effects or health concerns are quickly identified and addressed. The study staff will be available to answer questions and provide support, ensuring participants and their caregivers feel safe and informed throughout the study.

Is participating in this study mandatory?

Participation in this study is voluntary. If participants meet the criteria and decide to enrol, they can choose to leave the study at any time without needing to provide a reason.

To learn more, visit the clinical study website at teenasthmastudy.com or scan the QR code.
You can also call your local study site at the number below.

Study site contact details:
The study team can schedule a screening appointment to explain the study in detail.

Notes