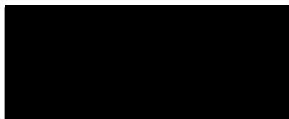


Visit Guide



Welcome to the [REDACTED] Trial!

Thank you for joining this clinical trial. Your participation will make it possible for researchers to learn more about an investigational oral pill, called [REDACTED] that may potentially treat asthma.

How to Use This Guide

This guide has helpful information about [REDACTED] and the visits and tests that are part of this clinical trial. There is space for you to take notes about your visits and write down your questions. If you have any questions, please contact the [REDACTED] Trial site staff. You can also look at the participant informed consent form for detailed information about this trial.

Trial visits are an important part of your participation, so please try to keep your appointments. If you need to reschedule, please call the site staff as soon as possible.

Contact Details

[REDACTED]

How Long Will the [REDACTED] Trial Last?

You are being asked to take part in the [REDACTED] Trial for about 21 weeks and to attend about 8 visits. The trial has 3 parts.

After completion of this trial, you may have the opportunity to join an open-label extension (OLE) trial that lasts about 1 year. "Open-label" means that you will know what trial treatment you are receiving. In the OLE trial, all participants will receive the trial drug.

Trial Timeline

Screening: Up to 5 weeks – about 1 visit

- 1 blood draw
- 1 urine test
- 3 breathing tests
- up to 4 questionnaires
- 1 electrocardiogram (ECG)*

You already signed the informed consent form and completed this screening. A trial doctor tested you to decide if this trial is a good match.

Double-blind treatment: 12 weeks – about 6 visits

- 5 blood draws
- up to 6 urine tests
- 18 breathing tests
- up to 14 questionnaires
- 2 ECGs*
- 2 nasal brushings (optional)

Now that you have joined the trial, you will be assigned randomly, like rolling dice, to get either the trial drug or a placebo, and will attend regular site visits. A placebo looks like the trial drug but contains no medication.

- "Double-blind" means you and the trial doctor will not know if you are receiving the trial drug or placebo. However, the trial doctor can quickly find out if needed.
- There is a 75% chance you will be assigned to the trial drug and a 25% chance you will be assigned to placebo.

Follow-up: 4 weeks – about 1 visit

- 1 blood draw
- 1 urine test
- 3 breathing tests
- up to 4 questionnaires
- 1 ECG*

The trial team will monitor your health after you stop taking your assigned trial pills (investigational drug or placebo).

If you choose to enroll in the extension and it is available, you will not complete this follow-up period. Week 12 will be your last visit for the [REDACTED] Trial before enrolling in the OLE trial.

*This test measures the heart's electrical activity.



Early Withdrawal from the Trial

Joining this trial is your choice. You may choose not to take part in the trial or leave the trial at any time.

Your participation may also be stopped by the trial doctor for any reason without your consent.

If you leave this trial, you will be asked to return to the trial site for a final visit, where the trial staff will perform follow-up tests and talk to you about your next steps after leaving the trial.

If your circumstances change throughout the study and you find you need additional support, please reach out to the study site, as they may be able to help.

Participants in the [REDACTED] Trial will receive:

- The trial drug or placebo and trial-related procedures at no cost.
- Payments to cover trial-related time and travel.
- Support from your trial doctor and site staff, who will check on your health while you are in the trial.



About the Investigational Trial Drug

There are several available treatment options for asthma. For people who have moderate to severe eosinophilic asthma, however, these treatments are sometimes not enough. Many of these treatment options may not be accessible, preferred, or effective for some people.

The [REDACTED] Trial is researching an investigational trial drug called [REDACTED] to find out if it may be a potential oral pill treatment option for eosinophilic asthma. [REDACTED] is a pill that researchers believe works differently from other asthma medications. It may potentially help the body get rid of certain proteins, called STAT6, that can contribute to airway inflammation in people with asthma. [REDACTED] finds and breaks down STAT6, the same way the body normally cleans up things it does not need. Researchers think that [REDACTED] may be a potential treatment option for people with moderate to severe asthma.

In this trial, [REDACTED] is being compared to a placebo. Placebos are very important in clinical trials, as they give scientists a basis to compare the trial drug to. This helps achieve the most accurate results.

[REDACTED] is used for research purposes only and is not yet approved to treat asthma outside of clinical research. It has been tested for safety in previous clinical trials and no serious side effects were reported or observed in those trials. However, further side effects of [REDACTED] may be unknown. Full details on potential side effects and risks of the trial drug can be found in the informed consent form. Your trial doctor will explain these to you.

Trial Reminders

Tell the site staff, including your trial doctor, about all medications you are taking. This includes all prescription drugs, over-the-counter medications (for common pain, cold, etc.), vitamins, herbal supplements, vaccines, and other kinds of therapies.

While in the trial, please:

- Do not take part in any other clinical trials. If you have questions, ask your trial doctor.
- Give correct information about your medical history and current medical condition.
- Tell the trial doctor about any health problems you have during the trial.
- Do not take any other medications unless the trial doctor has approved for you to take them beforehand. Do not stop taking any medications without first discussing with the trial doctor.
- Follow your trial doctor's instructions before performing breathing tests.
- Do not eat or drink anything with grapefruit or Seville oranges during the trial.
- For 48 hours before each blood sample collection, do not do any heavy exercise like heavy lifting, lifting weights, or aerobics.
- Use appropriate contraceptive (birth control) methods throughout the trial, as directed by your trial doctor.
- Be sure to tell the trial doctor immediately if you or your partner becomes pregnant during the trial.
- Continue to see your healthcare providers and tell them you are part of this trial.
- Ask your trial doctor or site staff if you have any questions.

Background Asthma Medication Instructions

[illegible]

Please make sure to leave your trial pills in their original container throughout the course of the trial.

At-Home Responsibilities

You will be asked to complete some tasks at home throughout the trial. These include:

- **IMPORTANT:** Taking your assigned trial pills at the same time every day, with or without food
- Completing the eDiary as directed by the trial site staff every day, recording when you take the assigned trial pills and when you use any asthma rescue medication
 - It is important to complete your dosing eDiary accurately every day. If you accidentally miss a dose, answer “No” to the question “Did you take your trial pills today?” and notify your trial site.
- Saving all empty trial pill containers



Your Trial Site Visits

The next few pages will tell you what to expect at each visit to the trial site. Please ask the trial doctor or trial site staff if you have any questions.

Visit Checklist

Please bring the following with you to all trial visits:

- A list of all medications you have taken, including any asthma rescue medication
- A note of any new or worsening symptoms or questions
- Your eDiary
- Empty containers and any unused assigned trial pills

Report any side effects or health problems you are having to the trial doctor immediately, even if you don't think they are important or related to the trial procedures. Please do not wait for your next scheduled visit to reach out.

Note: It is important you attend all trial visits. If you need to reschedule a visit, please contact the trial site staff as soon as possible. If you are having difficulty making appointments or following at-home requirements, please reach out to the trial team so they can help support you throughout the trial.

Thank you. We sincerely appreciate your time and commitment to this clinical trial.

What Tests Will Be Performed?

The trial doctor will perform certain procedures and tests at each of the trial visits. Some of these are described here.

-  **Review of medications and how you've been feeling:** A member of the trial site staff will ask you questions about your health, how you are feeling, and any medications you have taken since your last visit. They will also ask you about any asthma-related healthcare appointments.
-  **Randomization:** You will be randomly assigned, like rolling dice, to get either the trial drug or placebo during the double-blind treatment period.
-  **Physical exam:** A standard exam, including height and weight measurements if needed, will be done to check your overall health.
-  **Vital signs:** Your body temperature, blood pressure, breathing rate, and heart rate will be measured.
-  **Electrocardiogram (ECG):** This test measures your heart's electrical activity to make sure it is working properly.
-  **Blood and urine sample collection:** You will have samples of blood and urine collected for laboratory tests to test your health.
-  **Pregnancy test:** If you are an individual who can become pregnant, you will be tested for pregnancy.
-  **Breathing tests:** You will breathe into devices that test the amount of air you have in your lungs, how well you move that air, and tests for inflammation in your lungs. You may perform some of these tests before and after use of your inhaler.

 **Questionnaires:** You will be asked some questions about your asthma symptoms, general health, emotional well-being, and social well-being.

 **Nasal brushing (optional):** A member of the trial site staff will use a swab to collect cells from the inside of your nostril. This sample may help researchers better understand the role that genes play in asthma.

 **Dosing of trial pills:** You will take your trial pills at the same time every day. On visit days, you will take your pills at the site, so do not take them at home.

 **Trial pills check:** The site staff will record how many trial pills you return and will give you more, if needed.

Prior to certain breathing tests, you should avoid:

- **Strenuous exertion for at least 30 minutes**
- **Eating a large meal for at least 2 hours**
- **Restricted medications**

You will be asked not to take certain asthma medications for a period of time before breathing tests. The trial team will tell you which medications and for how long.

Please make sure to leave your trial pills in their original container throughout the course of the trial.

Double-Blind Treatment Period

Visit 2 (Day 1)

Date: __/__/____ Time: _____

This visit will last about: _____

- ☐ Review of eligibility, medications, and how you've been feeling
- ☐ Randomization
- ☐ Physical exam
- ☐ Vital signs
- ☐ ECG
- ☐ Blood sample collection
- ☐ Urine sample collection
- ☐ Pregnancy test (if applicable)
- ☐ Breathing tests
- ☐ Nasal brush (optional)
- ☐ Questionnaires
- ☐ Trial pills check
- ☐ Trial pills dosing

Remember to:

- Take your assigned trial pills every day
- Complete the eDiary every day
- Save empty or unused trial pill containers to bring to your next visit

If you miss or skip any doses, please reach out to the trial site for guidance.

Visit 3 (Week 1)

Date: __/__/____ Time: _____

This visit will last about: _____

- ☐ Review of medications and how you've been feeling
- ☐ Vital signs
- ☐ Blood sample collection
- ☐ Breathing tests
- ☐ Questionnaires
- ☐ Trial pills check
- ☐ Trial pills dosing

Notes

Please make sure to leave your trial pills in their original container throughout the course of the trial.



Double-Blind Treatment Period (cont'd)

Visit 4 (Week 2)

Date: __/__/____ Time: _____

This visit will last about: _____

- ☐ Review of medications and how you've been feeling
- ☐ Vital signs
- ☐ Blood sample collection
- ☐ Breathing tests
- ☐ Questionnaires
- ☐ Trial pills check
- ☐ Trial pills dosing

Notes



Visit 5 (Week 4)

Date: __/__/____ Time: _____

This visit will last about: _____

- ☐ Review of medications and how you've been feeling
- ☐ Vital signs
- ☐ Blood sample collection
- ☐ Urine sample collection
- ☐ Pregnancy test (if applicable)
- ☐ Breathing tests
- ☐ Questionnaires
- ☐ Trial pills check
- ☐ Trial pills dosing

Please make sure to leave your trial pills in their original container throughout the course of the trial.



Double-Blind Treatment Period (cont'd)

Visit 6 (Week 8)

Date: __/__/____ Time: _____

This visit will last about: _____

- ☐ Review of medications and how you've been feeling
- ☐ Vital signs
- ☐ Blood sample collection
- ☐ Urine sample collection
- ☐ Pregnancy test (if applicable)
- ☐ Breathing tests
- ☐ Questionnaires
- ☐ Trial pills check
- ☐ Trial pills dosing

Notes



Visit 7 (Week 12)

Date: __/__/____ Time: _____

This visit will last about: _____

- ☐ Review of medications and how you've been feeling
- ☐ Physical exam
- ☐ Weight and height measurements
- ☐ Vital signs
- ☐ ECG
- ☐ Blood sample collection
- ☐ Urine sample collection
- ☐ Pregnancy test (if applicable)
- ☐ Breathing tests
- ☐ Nasal brushing (optional)
- ☐ Questionnaires
- ☐ Trial pills check
- ☐ Trial pills dosing

Please make sure to leave your trial pills in their original container throughout the course of the trial.



Follow-Up Period

Visit 8 (Week 16)

Date: __/__/____ Time: _____

This visit will last about: _____

- ☐ Review of medications and how you’ve been feeling
- ☐ Physical exam
- ☐ Vital signs
- ☐ ECG
- ☐ Blood sample collection
- ☐ Urine sample collection
- ☐ Pregnancy test (if applicable)
- ☐ Breathing tests
- ☐ Questionnaires

Notes



Early Termination

If you stop the trial early, you will be asked to complete this visit.

Date: __/__/____ Time: _____

This visit will last about: _____

- ☐ Review of medications and how you’ve been feeling
- ☐ Physical exam
- ☐ Weight and height measurements
- ☐ Vital signs
- ☐ ECG
- ☐ Blood sample collection
- ☐ Urine sample collection
- ☐ Pregnancy test (if applicable)
- ☐ Breathing tests
- ☐ Questionnaires
- ☐ Trial pills check

Please make sure to leave your trial pills in their original container throughout the course of the trial.

Unscheduled Visit

If needed for any reason, the trial doctor may schedule an additional visit for you.

Date: ____/____/____ Time: _____

This visit will last about: _____

- ☐ Review of medications and how you've been feeling
- ☐ Physical exam
- ☐ Weight and height measurements
- ☐ Vital signs
- ☐ ECG
- ☐ Blood sample collection
- ☐ Urine sample collection
- ☐ Pregnancy test (if applicable)
- ☐ Breathing tests
- ☐ Questionnaires
- ☐ Trial pills check
- ☐ Trial pills dosing

Please make sure to leave your trial pills in their original container throughout the course of the trial.

Notes



Thank You

Thank you for choosing to join the [REDACTED] Trial. Your participation is contributing to developing future treatment options for people living with asthma. Clinical research would not be possible without volunteers like you.

We hope this guide is helpful during this trial. If you need more information, have any questions, or find it hard to follow the requirements of the trial, please reach out to the trial doctor or trial site staff.



Notes

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Notes

[illegible]



[REDACTED]

[REDACTED]