



UNCONTROLLED ASTHMA? JOIN US

Read how the LEVANTE study
wants to help you gain back
control over your asthma



A new clinical study

To find out if new treatments are better for people compared to what is currently used day-to-day, scientists use a carefully designed type of research called a **clinical study**.

LEVANTE is a new clinical study looking at a potential new treatment to help people with asthma, who are at a high risk of having a flare-up of symptoms.

You have been given this pamphlet because your doctor thinks this study might be right for you.

The purpose of this pamphlet is to help you understand a bit more about LEVANTE, the investigational treatment in this study, and what would be required of you if you decide to take part.

Please remember that taking part in a clinical study is always your choice.

You can decide to stop taking part at any time during the study and it will not affect the care you receive.

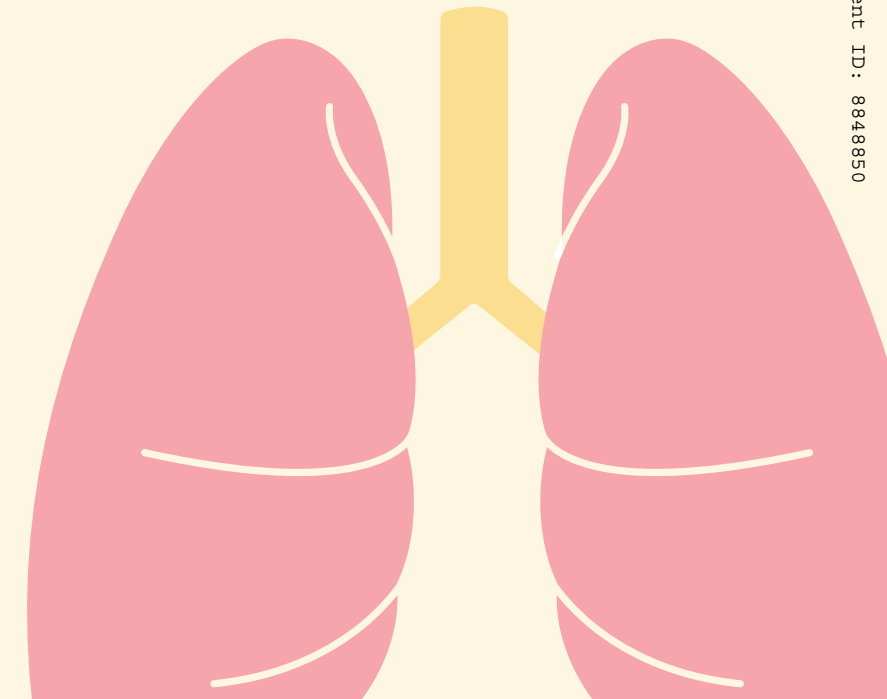
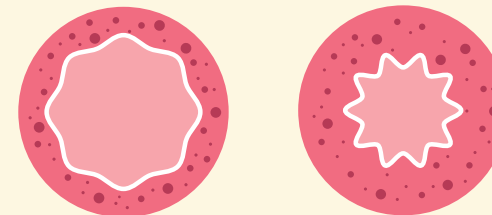
What is the purpose of LEVANTE?

There are currently a lot of medicines used to help manage the symptoms of asthma, such as inhaled corticosteroids or long-acting bronchodilators.

Some people with asthma may still experience periods where their asthma symptoms suddenly worsen. These periods are known as a **flare-up** or **exacerbation**.

LEVANTE is looking at whether a new investigational treatment called **AZD8630** can reduce the symptoms of asthma and prevent future worsening of symptoms or exacerbations.

Normal airway **Inflamed airway**





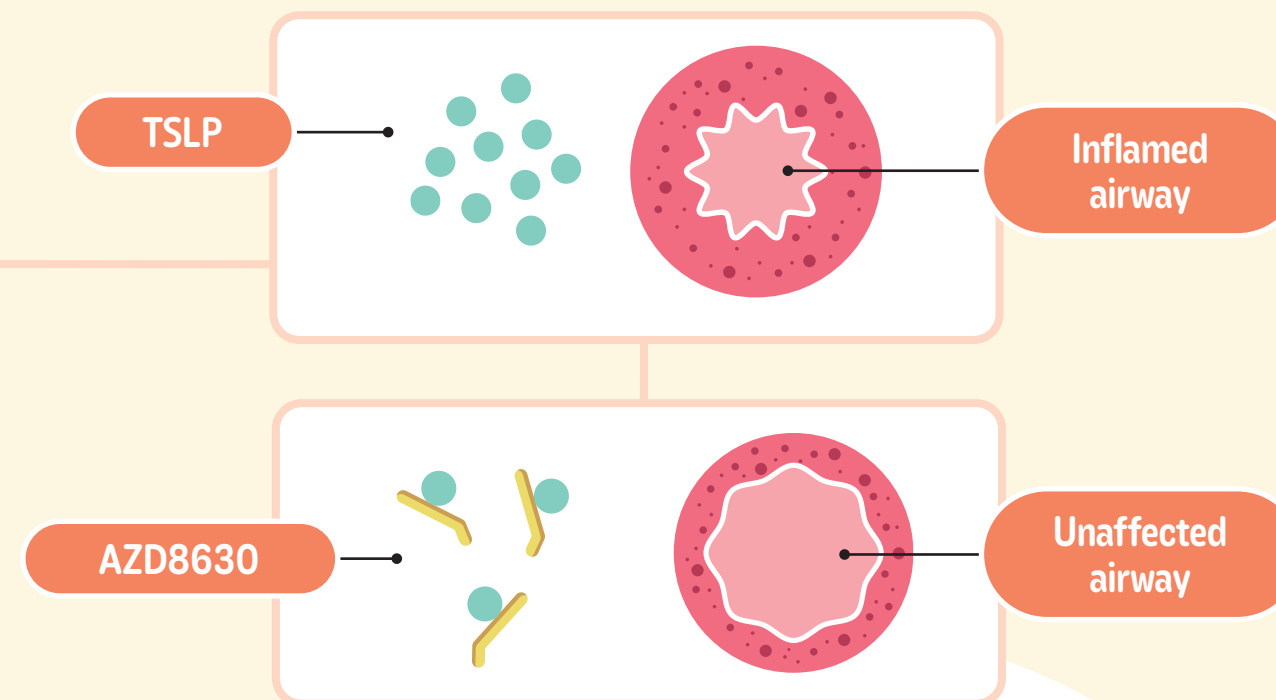
How does AZD8630 work?

When a person with asthma is exposed to a trigger, such as dust or pollen, the cells in the airway release a molecule called **TSLP**.*

AZD8630 works by sticking to TSLP. This stops it from working and may reduce inflammation and the symptoms of asthma.

This may **help to reduce inflammation** in the airways and improve the symptoms of asthma.

*TSLP stands for thymic stromal lymphopoietin.
You do not need to remember this, but it is here for your reference.



AZD8630 will be taken through an inhaler

You will be shown how to use this new inhaler during screening.

What can I expect if I take part in this study?

LEVANTE is split into three main parts and is expected to last for around 17 weeks



Screening & run-in period

2 clinic visits over 4 weeks

During screening, you will have tests and assessments to check if the study is right you.

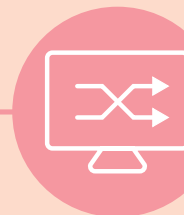
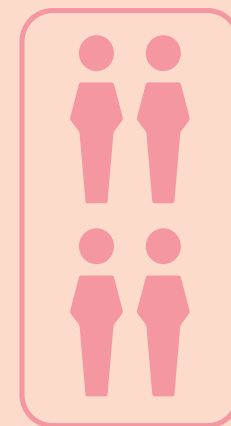
The run-in period will then include some assessments at home whilst you take your current medication. This will take two weeks to complete, after your screening tests and assessments.



Treatment

8 clinic visits over 12 weeks

If the study is right for you, you will be placed at random into **one of four** treatment groups. 3 groups of AZD8630, each with a different dose, and 1 group of placebo treatment.



Group 1
AZD8630



Group 2
AZD8630



Group 3
AZD8630



Group 4
Placebo

A placebo is a treatment that looks like AZD8630, but **does not** contain any **active medicine**. This will help to compare the effect of AZD8630 as well as keep the study fair and unbiased.

Everybody will keep taking their current asthma medication throughout the study, no matter which treatment group they join.



Follow-up

1 clinic visit, 8 days after last treatment dose

After treatment has finished, you will be invited back to the study clinic for one final visit. This is so the study team can continue to monitor your health and well-being.

If you decide to take part in this study, you will be asked to:



Visit the study clinic regularly

At least 8 times throughout the study. At these visits you will have some tests and assessments to monitor your health and well-being whilst taking the study treatment

You will have the option to have some visits virtually, where you are able to stay at home



Take AZD8630 or placebo regularly

Use your study inhaler to take your dose of AZD8630 or placebo as instructed by your study doctor



Tell us about your symptoms and how your new inhaler is working

You will also need to record any symptoms you may experience in a symptom diary, complete daily questionnaires, and let the study team know if you have any problems using your new inhaler



Attend the follow-up visit

LEVANTE also has an optional safety extension period. This will continue on from the treatment period, meaning that if you want to take part, you will continue taking AZD8630 or placebo for up to 40 additional weeks (52 weeks in total).

If this is something you would like to do, please speak with the study team, and they will be able to give you more information.

Just for your information

You and your study doctor will **not** know which treatment you are receiving. This is to prevent any bias when the study team are looking at the results of this study.

In the unlikely event of an emergency, your study doctor can find out what treatment group you are in, quickly.

We understand that taking a placebo may cause some patients to worry. AZD8630 is an ‘add-on’ treatment. This means that **everybody** will keep taking their current asthma medication, including if they are in the placebo group.



As with all medicines, there may be some side effects associated with AZD8630. Please speak to a member of the study team if you would like more information on the possible side effects.



All study related visits, tests, and study treatments will be provided at no additional cost to you. If applicable, you will be reimbursed for some payments you make during the study, for example, parking.

If you have any questions about the study, please feel free to contact the study team. You can also find more information about this study and what will be required of you in the informed consent form (ICF).

How can I take part?

If you would like to take part in this study, then please speak to your doctor. They will be able to give you more information and answer any questions you may have.

Please feel free to note down the contact details for the study team in case you have any more questions about the study after you have spoken with them.

Study doctor

Name:

Phone:

Address:

Email:

Fax:

Notes



We would like to thank you
for considering taking part
in LEVANTE.

The findings from this study
will be used to help develop
further treatments for people
with asthma, like yourself.