



vathos

Do you have asthma?

VATHOS is a clinical study
for people with asthma that
is not well controlled.

This pamphlet will give you some
information about the study and
how you may be able to take part.

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What is a clinical study?

A clinical study is a type of research used by doctors and researchers to find out whether a medicine is safe and works well in people with a particular medical condition.

It allows researchers to explore whether a medicine has any side effects and see if it works better than the treatment a patient would normally receive for their condition.

The information gained from clinical studies may benefit you or others like you in the future.

Taking part is entirely **voluntary**. Anyone who joins a study can leave at any time and for any reason.

What is the VATHOS clinical study?

VATHOS is for people with asthma whose symptoms are not fully controlled with their current inhaler treatment.

It will see whether an investigational type of inhaler treatment called **BFF MDI** may help people with this type of asthma.

The study will also be used to help better understand asthma and other commonly linked conditions.



What is asthma?

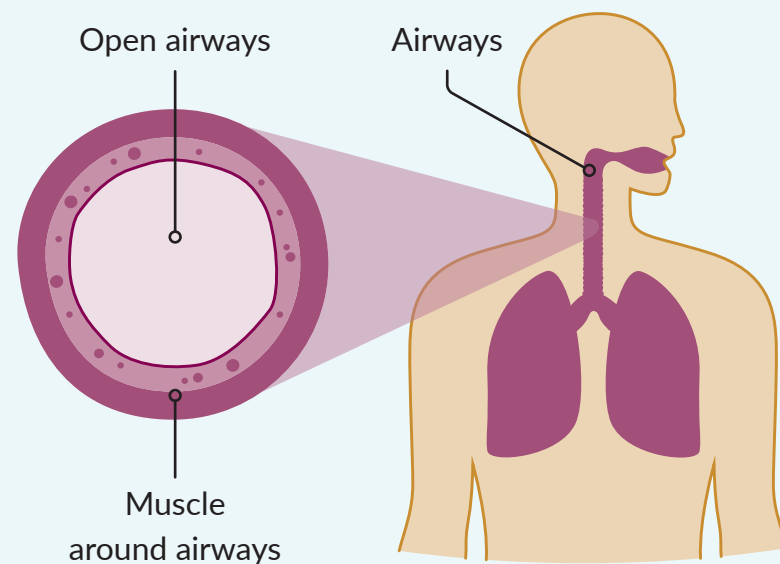
Asthma is a condition that can make breathing difficult.

In asthma, your **airways become narrower**, which makes it harder to breathe. This happens because the airways become **swollen** and **inflamed**.

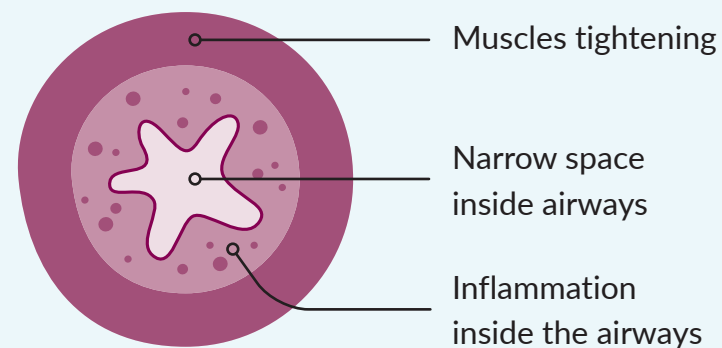
Over time, this can cause the **walls of your airways to get thicker**. This means there is **less space for air to flow in and out**, making it more difficult to breathe.

This narrowing is more likely to happen if your symptoms are not fully controlled by your treatment.

Normal airways



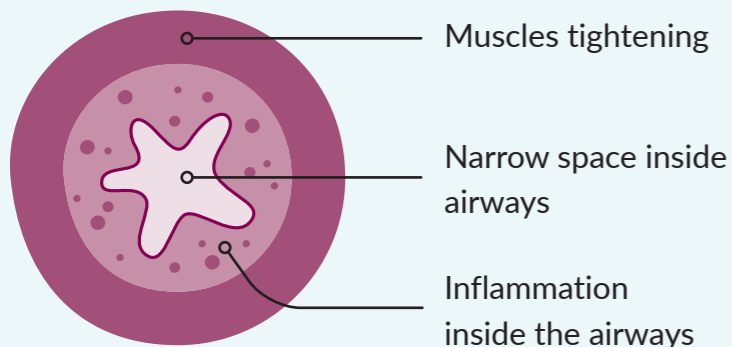
Airways in people with asthma



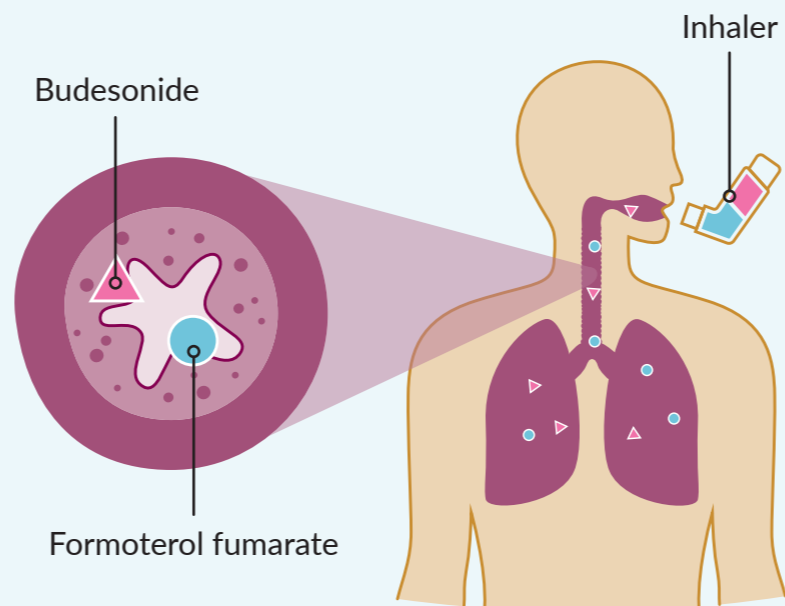
What is the new inhaler treatment?

In VATHOS, researchers are trying to learn more about BFF MDI. BFF MDI is a metered dose inhaler (MDI) that can spray a particular amount of medicine into the airways.

Before BFF



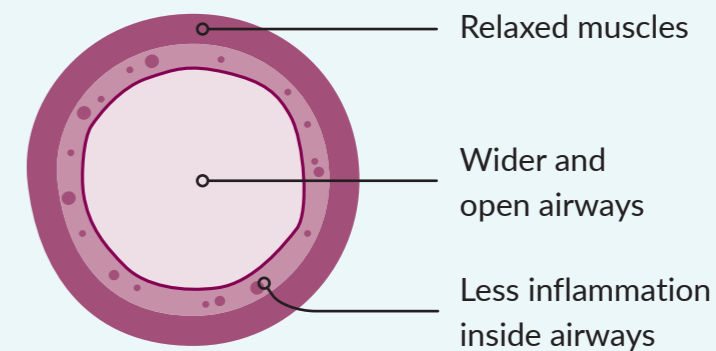
With BFF

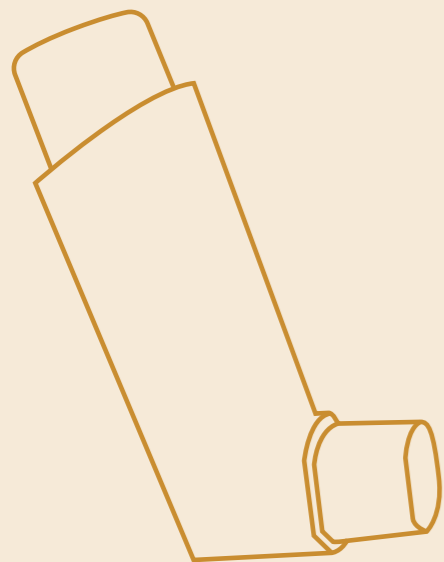


The inhaler contains 2 medicines called **budesonide** and **formoterol fumarate (BFF)**. Both of these medicines are already approved to treat asthma, either on their own or in combination with other medicines.

The 2 medicines are designed to work together to **reduce inflammation, relax the muscles in the airways** and help keep the **airways open**.


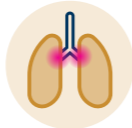

After BFF





Who can join?

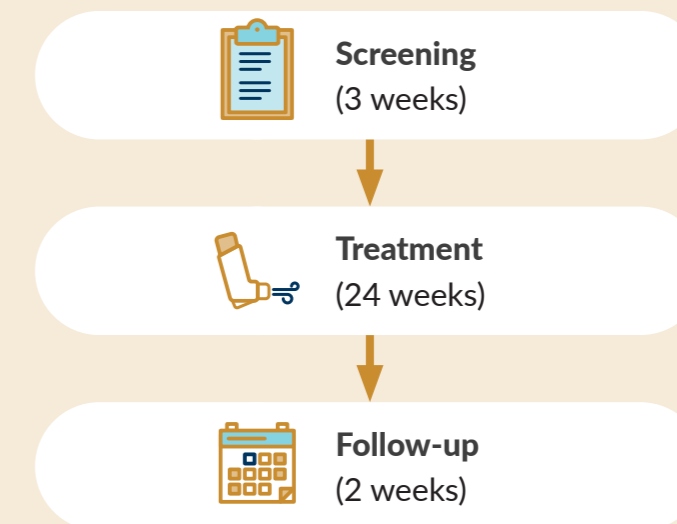
You may be able to join the study if you:

-  **12+** Are between 12–80 years of age
-  Have been diagnosed with asthma
-  Have been using the same dose of ICS* or ICS/LABA[†] inhaler medication every day for at least 8 weeks

*ICS = inhaled corticosteroid; [†]LABA = long-acting beta agonist.

What is involved in the study?

VATHOS is split into 3 parts: **screening**, **treatment** and **follow-up**. They will take place over a maximum of **29 weeks** (around 7 months).



Screening

Screening is used to confirm whether you are suitable to take part in the treatment period of the study. The screening period will last about **3 weeks**, and you will be asked to attend **3 clinic appointments**.

During screening you will need to have some tests and assessments. These may include:



Medical history



Blood tests



Physical examination



Urine test



Breathing tests
(lung function tests)



Heart tests

If you are not able to join the study, your study doctor will explain the reasons why following these tests. They will also explain about any other treatment options you may have.

Treatment

If the study is suitable for you, you will enter the treatment period, which lasts for **24 weeks** (6 months).

There are 4 treatment groups, and the group you join will be decided randomly by a computer. Depending on the group you are in, you will receive either:

Group 1

BFF MDI (high dose budesonide)

▲ Budesonide 320 µg

● Formoterol fumarate 9.6 µg



Group 2

BFF MDI (low dose budesonide)

▲ Budesonide 160 µg

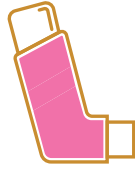
● Formoterol fumarate 9.6 µg



Group 3

BD MDI

▲ Budesonide 320 µg



Group 4

Symbicort® Turbuhaler®

▲ Budesonide 320 µg

● Formoterol fumarate 9 µg



Throughout the study, you will also need to carry out some assessments at home.

These include:



Recording any asthma symptoms and medication you take on an electronic device called an **eDiary**



Recording your lung function using a **peak flow meter device**

- A peak flow meter is a small device that you breathe into. You may have used it before to check how well your asthma is being controlled. If you haven't used one of these before, don't worry – the study team will be able to help

This study is **double blind**. This means that neither you nor your doctor will know which group you are in.*

During this part of the study, you will need to use your study inhaler **twice a day** and attend **2 virtual** and **5 in-person appointments**. These will allow the study team to monitor your asthma and general wellbeing.

Some of these appointments will involve you having some tests and assessments, similar to those you will be asked to have during screening.

*If there is an emergency that requires knowing which group you are in, the study doctor can find this out quickly.

Follow-up

When your study treatment is stopped, for any reason, you will be asked to attend a follow-up telephone appointment 2 weeks after your last dose of study treatment.



Follow-up appointments are very important so that the study team can continue to monitor your wellbeing and easily act if any further care is needed.

Are there any side effects?

As with all medicines, some side effects might be associated with the treatment you receive during this study.

If you decide to join, your doctor will discuss these with you in more detail.

The study team will continually monitor your health and wellbeing during the study. They will always put your safety first.

**Thank you for reading this pamphlet.
We hope you found it useful.**

The findings from this study may help you and others diagnosed with asthma in the future.

If you are interested in taking part in the VATHOS study, please speak with your doctor for more information.