Researching Sustainable Asthma Care

Your guide to the D6933C00002 clinical study

This short pamphlet **will help you** to understand more about what to expect now that you have joined.

Study code: D6933C00002
Version no.: 1.0
Date: 06/06/2024
US-enUS

We know that improving sustainability and equity in asthma care is important to you.

That's why our clinical study is investigating a **new propellant** to help asthma treatments become more environmentally friendly, and ensure they stay accessible to people who need them.

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What is the D6933C00002 clinical study?

Asthma is commonly treated with inhalers that contain medicines which help to reduce inflammation and swelling in the airways. To deliver these medicines into the lungs, these inhalers use a special type of medical gas known as a **propellant**. A common approved propellant is called **HFA**.

HFA propellant is known to contribute to global warming and many countries will soon have laws which stop it from being used in inhalers.

This means that more environmentally friendly propellants are needed to make sure asthma treatment can continue to be available globally.

A **new propellant called HFO** that is more environmentally friendly than **HFA** is currently being investigated.

The inhalers in this study will contain a treatment called **budesonide and albuterol (BDA)**. BDA is already a well-established treatment for asthma.

The study will assess whether BDA using HFO is as good at delivering BDA into the lungs as the BDA using HFA, and is as effective at reducing airway inflammation.

Why have you been asked to join?

You have been asked to take part in this study because you have asthma that is well-controlled, and albuterol or salbutamol improve your lung function.

You may also be motivated to take part in the study because you have a personal interest in environmental sustainability.

What does the study involve?

The study is expected to last **14–15 weeks** and is divided into 3 key parts, known as screening and run-in, treatment, and follow-up:

Screening and run-in

(Around 2 weeks, 1 visit)

You will come to the study clinic for **tests and assessments** to make sure you meet the criteria for taking part and confirm that the study is right for you.

You will also stop taking any of your usual asthma treatments and start taking a placebo inhaler **4 times a day**. The placebo looks like the study treatments containing BDA and is given in the same way, but it does not contain any active medicine. Placebos help us find out whether a medicine is working.

We understand that taking a placebo might cause you to worry. You will be given a rescue inhaler that you can use at any time if you feel it is needed. This will be albuterol or salbutamol depending on which country you live in.

Your health and safety is the study team's priority, and you have been chosen for this study because your asthma is well-controlled.

As well as regular clinic visits, you will be asked to **track your symptoms** in an electronic diary (eDiary) every day. This is so the study team can monitor your health and well-being closely and help you quickly if you need it.

Your study team will train you on how to use and clean your inhalers, and how to record any symptoms using your eDiary during this time.

Treatment
(Around 12 weeks, 4 visits)

After taking the placebo inhaler for 2 weeks, you will then start the treatment part of the study.

You will join **1 of 3 treatment groups** and start getting treatments.

The groups include:

Group A1 and A2

Treatment 1: BDA inhaler with **new propellant** (BDA MDI **HFO**)

Treatment 2: BDA inhaler with **current** propellant (BDA MDI **HFA**)

Group B

Treatment 1: BDA inhaler with **new** propellant (BDA MDI **HFO**)

Treatment 2: BDA inhaler with **current** propellant (BDA MDI **HFA**)

Treatment 3: Placebo inhaler with **current** propellant (Placebo MDI **HFA**)

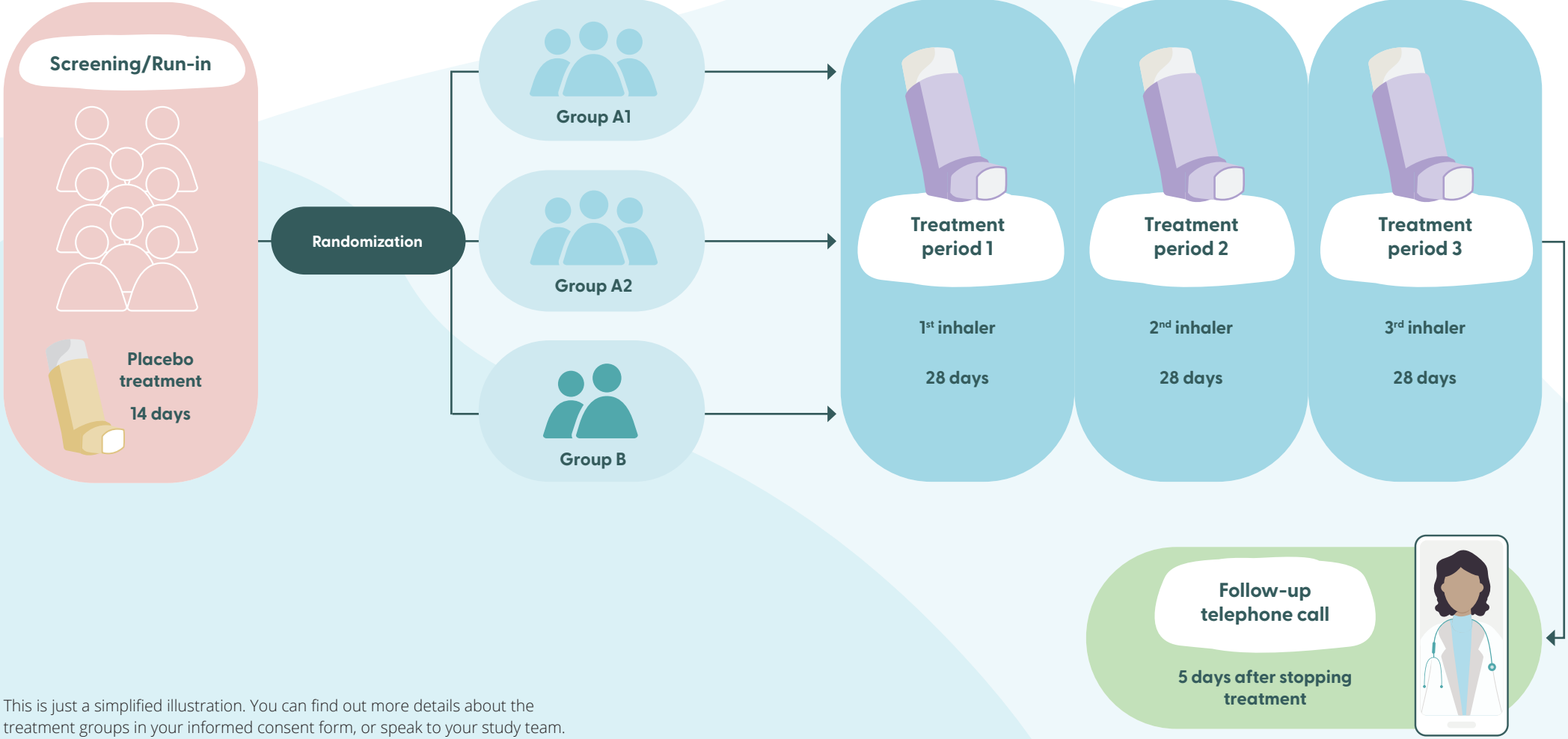
Depending on which group you join, **you will receive 3 study treatments** in a different order **every 28 days (around 4 weeks)**.

All 3 treatment groups will have inhalers containing active medicine, but Group B will also contain a placebo. This means you will have a **1 in 3 chance** of receiving placebo during one of the 28 day treatment periods.

You can find out more about the study plan in a simplified illustration on the next page.

Neither you nor your study team will know which treatments you are taking, or what sequence they will be given in. This is known as being a **double-blind** study, and it helps to keep the study fair and unbiased.

You will also have **tests and assessments** at the study clinic and at home during the treatment part. You can find out more about these in the "**What tests and assessments will I have during the study?**" section.



This is just a simplified illustration. You can find out more details about the treatment groups in your informed consent form, or speak to your study team.

If you experience any asthma symptoms, **please continue to use your rescue inhaler** during treatment and track your symptoms in your eDiary.

Your study team will also be able to use the information you log in your eDiary to **monitor your health and well-being outside of your study clinic visits**.
If your symptoms change, your study doctor will receive a notification. This will allow them to **help you quickly**, if you need it.

Follow-up

(Around 5 days)

A **final telephone** call around **5 days after** you stop taking your treatment.

Follow-up calls allow the study team to check your health and well-being after you have finished taking the study treatment. It is an important way of finding out more about how the study treatment you have taken affects both you and your asthma.

During the appointments, you can also ask questions or discuss any symptoms you may be experiencing with your study doctor.

What tests and assessments will I have during the study?

Tests and assessments are important for the study team to be able to monitor your health and well-being, and how the treatment is working in your body. These will happen during screening and run-in, treatment, and follow-up.

Some of these will be during your **clinic visits**, and others will be at **home**.

At the study clinic, the tests and assessments will include:

A physical examination

Height and weight

Vital signs (including blood pressure and pulse rate)

Blood tests (including a pregnancy test if applicable)

Heart test, called an electrocardiogram (ECG)

Asthma questionnaires

Lung tests, called spirometry

At home you will need to complete eDiary questionnaires every morning and evening. They include details about:

Your breathing symptoms

Peak flow readings

Rescue inhaler use

However, if you still have questions or would like some support to complete your daily eDiary, please don't hesitate to talk to them.

Frequently asked questions

What lifestyle adjustments will I need to make during the study?

You may need to make some small changes to your diet and lifestyle whilst you are taking part in the study. This is to make sure that the study team can accurately measure your health and well-being, and how well the study treatments are working for you.

Adjustments for the whole study

Continue to avoid:
Consuming any products which contain tobacco, nicotine (including e-cigarettes) or marijuana

Adjustments around clinic visits

Avoid:
Eating or drinking products which contain caffeine and xanthine **6 hours before**, and for the whole time you are at your study clinic visit

- These include products such as coffee, tea, cola drinks and chocolate

Drinking alcohol 24 hours before spirometry tests

Your study team will advise you when to expect clinic visits and spirometry tests so you can plan to make any adjustments.

What support will I get to help me attend the clinic visits?

You will have **4 visits** to the study clinic for tests and assessments during the treatment part of the study. To help make clinic visits as easy as possible, there will be an opportunity to **stay overnight** in the clinic or a nearby facility, such as a hotel, before each visit*.

This is to help minimize the need for travelling to and from the study clinic on these days. The study team hopes that providing accommodation may help to make your clinic visits as simple and convenient as possible.

To help minimize the need to use your rescue inhaler, the study team will also be able to **organize transport services** to and from the study clinic, even if you choose not to stay overnight.

You will be re-paid for your travel costs throughout the study.

*If you choose to stay overnight, you are encouraged to stay overnight for all 4 visits. This is so that the scheduled morning dose on the day of visits can be taken at a similar time each visit.

What should I do if I have any side effects whilst taking the study treatment?

Like all medicines, BDA MDI HFA inhalers can cause some unwanted symptoms, known as **side effects**. Common side effects (affecting **more than 1 in 100 people**) may include:

A white coating on your tongue and back of the throat caused by a yeast infection

Shaking/tremors

Headaches

Your heart beating faster than usual

Mild irritation in your throat

Cough and/or a hoarse voice

If you are taking the placebo, or the HFO propellant isn't as effective at delivering BDA into your lungs as the HFA propellant, there is a chance your asthma symptoms could get worse. If you do notice any changes, you can **use your rescue inhaler**.

Please be reassured that your study doctor will **monitor you closely** whilst you are taking treatment. Regular clinic visits and eDiaries will help them to identify any changes in your health and well-being quickly.

What happens if I change my mind?

Taking part in a clinical study is **always** your choice. You can change your mind or stop taking part at any time, for any reason. Stopping the study will not affect the quality of care that you receive.

If you would like to stop, please let your study doctor know as soon as you can. They will be able to discuss your options and next steps with you.

Notes

Notes

Thank you for your continued commitment to the D6933C00002 clinical study.

Your dedication will make a big difference to our research and contribute towards creating a more environmentally friendly future for asthma care.