

Participant Information Sheet For School-Age Children:

To be shown and read with parent/ caregiver

All backgrounds and abilities are welcome to take part!

You are being invited to take part in this study to help us find out if a combination inhaler can help to control your asthma better. A computer program will put you in one of two groups.

In group 1, you will be given a new red inhaler.

In group 2, we won't make any changes, you will have the same inhaler(s) which you normally have.

We will ask you and your parent/caregiver questions about your asthma. On the next pages we will explain what happens during the study.

What is a research study?

A research study is a careful experiment to find out the answer to an important question about health.

Why is this research study being done?

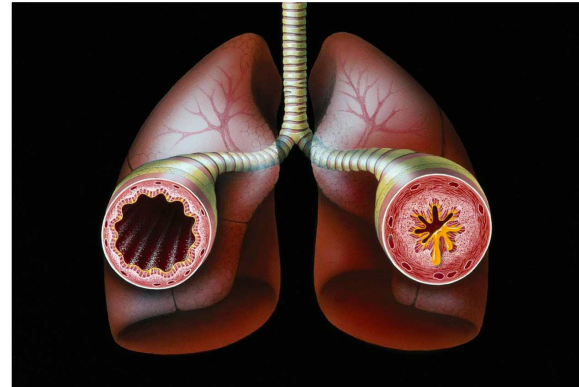
We want to find a better way to treat children with asthma. In this study, we will ask some children to use a combination inhaler. We will compare the combination inhaler to the normal inhaler(s) to see if one of them is better than the other.

What is asthma?

Asthma is an illness that makes it difficult to breathe. It might make you cough or wheeze. Asthma happens because the tubes in your lungs swell, get smaller and get thick liquid in them. Sometimes children

with asthma need to go to hospital or may not be well enough to go to school.

Here is a picture of lungs from a person that has asthma. You can see the tube on the right is swollen making it smaller and is blocked with thick liquid.

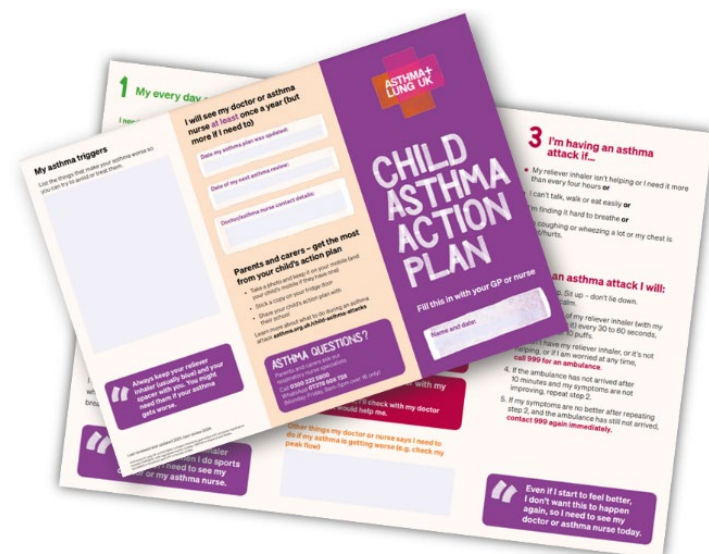


Where will the study take place?

The study appointments will be done at this hospital and by video/telephone calls. You will be asked to come to hospital twice: once at the start of the study and again after 1 year. We will also call you after 4 and 8 months to ask some questions about your asthma, make sure you have an up-to-date asthma plan and know how to use your inhalers.

What is an asthma plan?

An asthma plan tells you and your parent/caregiver how to take care of your asthma. It shows you what to do for your everyday asthma care (in green) and when you're feeling unwell (in orange and red). You can share this asthma plan with your family, friends and teachers so they know how to help you when you're not feeling well.



What will happen in this study?

You might be given a red inhaler. This will be your new reliever inhaler and some children will also take this inhaler every day as their regular inhaler. Or you might continue using the same inhaler(s) as usual. A computer program will help us to decide which group you will be in. This way, everyone has a fair chance to be in either group.

Group 1



Or

Group 2



1. Beginning - we will talk to you on a phone call

In the beginning, we will give you and your parent/caregiver a phone call. In this phone call, we will explain the study and ask your parent/caregiver some questions about your health and your asthma. This call is to check if you can take part in the study. It will take you about 30 minutes.

2. Visit 1 and Visit 4 - we will invite you to the hospital

You will come to the hospital to meet the doctor or nurse. They will tell you about the study and check if you are happy to join. They will ask you and your parent/caregiver more questions about your health and your asthma. They will measure your height. They will also make sure you know how to use your inhaler and give you your asthma plan. The visits will take you about 1-2 hours to complete.

[Visit 1 only] Some of you may also be given an electronic monitoring device to attach to the inhaler. This device can record how often you use your inhaler.

3. Visit 2 and Visit 3 – we will talk to you on a video call or by telephone

We will call you at 4 months and 8 months. We will ask you and your parent/caregiver questions about your asthma and answer any questions you have. It will take you about 30 minutes.

Who is taking part in this study?

We are inviting 1,352 children like you (6 to 11 years old) from all over the country to take part in this study.

How long will the study take?

You will be in this study for 1 year.



1,352 children with asthma
6-11 years old



676 children
Combination inhaler



676 children
Inhaler(s) you use now



Visit 1 - at the start

We will measure your height, take your saliva, ask you some questions and give you an asthma plan



Visit 2 & Visit 3 - at 4 and 8 months

We will ask you some questions



Visit 4 - at 1 year (end of study)

We will measure your height, take your saliva, and ask you some questions



Who will lead the study?

Dr Louise Fleming and her team at a University called **Imperial College London** are leading this study.

Do I have to take part?

No, you don't have to take part - it is up to you. We would like you to read this information sheet. If you agree to take part, we would like you to write your name on two forms if you're able to. We will also ask your parent/caregiver to write their name on the forms and give one back to us. You can still change your mind at any time. If you don't want to take part, just say no!

What if something goes wrong?

Your parent/caregiver will be able to follow the asthma plan. If you are unwell, they must take you to the doctor or hospital as they would normally do. The treatment you receive will not change. We will give you the name of the contact person in the study team if you become unwell and they should be told when this happens.

What if I don't want to do the research study anymore?

Just tell your parent/caregiver, doctor or nurse at any time. They will not be cross with you. You will still have the same care whilst you are at your doctor or hospital.

What if I want to complain about the study?

If you want to complain then you or your parent/caregiver can talk to Dr *[insert Principal Investigator's name]* or *[insert Nurse's Name]* at this hospital.

Will anyone else know I'm doing this study?

The people in our research team will know you are taking part. The doctor looking after you and their team at this hospital will also know and if you say it is OK, we will also inform your GP. No one else will know because we will not use your name or house address. You will get a study number which will be used instead of your name.

What happens to what the researchers find out?

When we collect your information we will make sure it is stored in a safe place and only the people doing the research study can look at it.

We will use the information we collect from you and other children like you, to find out more about asthma and which medicines are better. We will put the results from this study in medical magazines and on websites that doctors read.

Did anyone else check the study is OK to do?

This study has been checked by many people, to make sure it is alright. Scientists and experts on something called an Ethics Committee have checked everything before we started this study.

How can I find out more about this study?

Your parent/caregiver or other grown-up you trust may be able to answer your questions. The doctors and nurses looking after you can also help you find out more about the study. We also have a website where you can find more information (<https://careukstudy.uk/>).

Thank you for reading this 😊

Please ask any questions if you need to!