

## Participant Information sheet for parents

V4.0 22-3-2023

### CONTENTS - PART 1

Important things to know	Page 2
Why has my child been invited to take part?	Page 2
Why are we doing this research	Page 2
What will we have to do if we take part?	Page 3
Does my child have to take part?	Page 4
What happens if I change my mind?	Page 4
How will I know which group my child is in?	Page 4
What are the alternatives for treatment?	Page 5
What are the benefits of taking part?	Page 5
What are the benefits of taking part?	Page 5
What happens when the study stops?	Page 5
Will taking part be confidential?	Page 6
I'm interested in taking part, what do I do next?	Page 6
Information sheet part 2 - Detailed information about the conduct of the study.	Page 7

### How to contact us



If you have any questions please contact your GP practice.

Or you can speak to a study doctor by calling or sending a text to our central helpline: **07971307807**

**You are invited to take part in ASYMPTOMATIC – a trial to find out how best to use inhaled steroids to treat children with mild asthma**

### Part 1 - The purpose of the study

You are invited to take part in ASYMPTOMATIC – a study to find out how best to use inhaled steroids for children with mild asthma.

You have been provided with this information sheet as your child may be able to take part in this research.

Please take your time to read the information carefully.

Take time to consider whether or not you wish your child to take part. Please feel free to discuss the trial with your friends and relatives, your GP or the nurse at the practice involved in your child's asthma care.

Taking part is completely voluntary. If you do not want your child to take part then that is completely fine. Your usual care will continue as normal.

We would like to thank you for taking the time to read this information sheet. We hope you find it helpful.

## Important things to know

The aim of the ASYMPTOMATIC trial is to find out the best way to use inhaled corticosteroids (preventer inhaler) in children with mild asthma.

At the moment, children in the UK are advised to take their corticosteroid inhaler every day.

Although this approach appears to help prevent asthma attacks, it may not be needed in all children with mild asthma.

They could perhaps use a corticosteroid inhaler only on days when they have asthma symptoms, such as cough, wheeze, or shortness of breath.

This trial will measure if the number of asthma attacks is different between children who take their corticosteroid inhaler every day (the “daily” group) and those who take it only when they have symptoms (the “symptom-driven group”).

## Why has my child been invited to take part?

Your child has been invited to take part because they have asthma, which is felt to be mild (rather than moderate or severe).

This means they haven't had many asthma attacks this year, and the team at your GP practice has not been worried that their asthma has caused lots of problems with their health.

## Why are we doing this research?

Preventing asthma attacks is very important.

Inhaled corticosteroids prevent asthma attacks when taken every day. However, it is unknown whether children with mild asthma need to take inhaled corticosteroids every day.

In adults with mild asthma, studies have shown that taking inhaled corticosteroids only when you have symptoms works just as well as taking it every day. Doing so cuts the amount of inhaled corticosteroid you take dramatically, which can reduce the risk of side effects.

Adults with mild asthma are now being told to take their inhaled corticosteroids only on days when they have symptoms. However, we do not know if this is the right thing to do for children and young people.

The best way to find out is to do a research study, like ours.

Our study aims to compare two groups:

(1) children taking inhaled corticosteroids every day (daily) with (2) children taking them only when they have asthma symptoms (symptom-driven).

We want to see whether taking inhaled corticosteroids in a 'symptom-driven' way is a safe and effective way to prevent asthma attacks.

# What will we have to do if we take part?

A member of your GP practice will talk to you in more detail and answer any questions you may have. If you have had all of your questions answered and are happy to take part then you will be asked to sign a consent form. You will be given a copy of the consent form and this information sheet to keep.

You will not be required to attend any extra visits to the GP practice aside from those you would normally make. This is because we can see from your child's health records whether they have had any asthma attacks.

You will be asked to help your child fill out short surveys at four times in the study, the first when your child joins the study and then after 4 months, 8 months, and 12 months.

We expect the surveys to take less than 20 minutes to complete each time.

The surveys are completed online, so you will need access to the internet and a computer or tablet. You can also complete the surveys on a mobile phone but they may be more difficult to view.

Your local library will usually have free internet access if you need it.

We will send you a reminder by email when it is time to complete your surveys. You can also provide your mobile number if you'd like to receive an SMS reminder too.

As a thank you for completing the questionnaires we will send you a £5 gift voucher each time you complete all of the questionnaires for a particular timepoint. The gift voucher will be a code sent to you by email, within a few weeks of completing the questionnaires. The vouchers can be used in multiple stores online or on the high street.



	Baseline	4 months	8 months	12 months
Asthma Control Test-questions about asthma symptoms	✓	✓	✓	✓
CHU9D - quality of life questionnaire	✓	✓	✓	✓
Adherence questionnaire - questions about inhaler use	✗	✓	✓	✓
Gift voucher for completing all questionnaires	£5	£5	£5	£5

## Does my child have to take part?

If you do not want your child to take part in the study you do not have to give a reason and they will be given the same treatment that would normally be provided.

The standard of care your child receives now or in the future will be the same whether they take part or not.

## What happens if I change my mind?

Before you decide to take part, you and your child should be satisfied that you are happy to (1) use either daily inhaled steroids or symptom-driven inhaled steroids, and (2) complete the surveys when you join the study and then after 4 months, 8 months, and 12 months.

It is okay if you agree to take part in the study but later change your mind. You do not need to give a reason. Any reasons you choose to share may help us improve the way we run the study.

The clinical team may choose to withdraw your child if it is necessary for any reason. A decision not to take part or to leave the study will not affect the standard of care your child receives.

All information collected up until the time of withdrawal will be included in the study analysis, unless you request that it is removed.

## How will I know which group my child is in?

In research studies we often split patients up into groups to look at how different treatments work. Patients in one group get a different treatment than patients in another group.

In ASYMPTOMATIC children will be split into two treatment groups at random:

### **One group will receive “Daily corticosteroids”**

This means your child takes their inhaled corticosteroids every day, even if they feel well. This is what currently happens

### **The other group will receive “Symptom-driven corticosteroids”**

This means your child takes their inhaled corticosteroids only on days when their asthma is bad enough for them to use their blue reliever inhaler.

It is really important that each group has a similar mix of people in it so we know that if one group does better than the other it is very likely to be because of the treatment and not because there are differences in the types of people in each group.

We use a computer programme that puts people into groups ‘at random’ – you might hear this described as ‘randomisation’ or ‘random allocation’, but they all mean the same thing. Neither you nor your child’s doctor choose which group they are in.

In the ASYMPTOMATIC trial your child is equally as likely to be in the "Daily" group as the "Symptom-driven" group.

If you decide to take part in the trial a member of your GP practice will let you know which group you are in, and how your child should use their inhaler.

If you have a strong preference for one treatment over another you should talk to your GP about your preference and whether or not taking part in the ASYMPTOMATIC trial is right for you.

## What are the alternatives for treatment?

If you decide against your child taking part in ASYMPTOMATIC their usual asthma care will continue as normal.

## What are the benefits of taking part?

At present, the normal practice in preventing asthma attacks is to take corticosteroid inhalers in a "Daily" manner. We know this approach works at reducing asthma attacks.

However, we do not know if taking corticosteroids every day is necessary for all children with mild asthma. If children could take inhaled corticosteroids only when they needed them, without increasing the risk of asthma attacks, this would have advantages.

They would have a smaller amount of corticosteroid over the course of a year, and spend less time taking their inhalers.

## What are the risks of taking part?

Your GP will always be able to change or add to your child's asthma treatment if needed.

No additional tests or procedures will be involved over and above normal clinical care, apart from asking you to fill out some short surveys on four occasions over one year.

We have set up an independent team to monitor the results of the study, to check that children are not coming to harm.

## What happens when the study stops?

At the end of your child's participation in the study you will return to standard asthma care in discussion with your GP.

When all participants have completed their part in the study we plan to present the study results at scientific conferences and to publish them in medical journals so that we can explain to the medical community what our research results have shown.

The study, as a whole, is scheduled to end in August 2025 and we will make a summary of the results available on the study website as soon after this as possible. We will also send a summary of the study results to your GP.

Confidentiality will be ensured at all times and you and your child will not be identified in any publication.

## What happens when the study stops? continued

Any information derived directly or indirectly from this research, as well as any patents, diagnostic tests, drugs, or biological products developed directly or indirectly as a result of this research may be used for commercial purposes.

Neither you nor your child have any right to this property or to any share of the profits that may be earned directly or indirectly as a result of this research. However, in signing the consent form for this research, your child does not give up any rights that they would otherwise have as a participant in research.

## Will my child taking part in the study be kept confidential?

Yes. All the confidential information about your child's participation in this study will be kept confidential. Detailed information on this is given in Part 2 of this information sheet.

## I'm interested in taking part, what do I do next?

**Contact your GP practice to book an appointment and tell them that it's for the ASYMPTOMATIC study.**

This appointment will be to discuss the study further and confirm that your child is eligible to take part.

The best telephone number to contact your GP on is on the letter or email that you were sent with this information sheet.

OR

**Call or text our central study number to talk to a study doctor. You will be able to ask any questions you have about the study and find out about the next steps**

The central study number is:

**07971 307807**

If there is no answer please leave a message with your name and contact number and the study doctor will call you back.

Please also read the more detailed information on the next pages about how we will conduct the study.

## CONTENTS - PART 2

Who is running the study?	Page 7
How will you collect and use information about my child?	Page 8
What are my choices about how my child's information is used?	Page 8
Information sharing for other research.	Page 8
Where can I find out more about how my information is used?	Page 9
What if there is a problem?	Page 9
How to contact us	Page 9

## Part 2. Detailed information about the conduct of the study.

### Who is running the study?

Alder Hey Children's NHS Foundation Trust is the Sponsor of this study and is responsible for managing it. They have asked that the day to day running of the study is carried out by a team based at the Clinical Practice Research Datalink (CPRD), part of the Medicines for Healthcare Regulatory Agency.

A paediatric respiratory doctor, based at Alder Hey Children's Hospital, is leading the study supported by a team from across the UK, including GPs, asthma specialists, statisticians from the University of Liverpool, and health economics researchers from Bangor University,

The study has been reviewed by the Medicines and Healthcare Products Regulatory Authority, the Health Research Authority and the National Research Ethics Service to make sure that the study is scientifically and ethically acceptable.

This study is funded by National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme.

Your child's doctor will not receive any personal payment for including your child in this study but the GP practice will be reimbursed for the time staff spend on the study.

## How to contact us



If you have any questions please contact your GP practice.

Or you can speak to a study doctor by calling or sending a text to our central helpline: **07971307807**

## How will you collect and use information about my child?

Alder Hey Children's NHS Foundation Trust is the Data Controller for this study and will need to use information from you or from your medical records for this research project.

The University of Liverpool, Bangor University and Clinical Practice Research Data Link (CPRD) are data processors and will only use your data in a way approved by the Data Controller.

This information will include your child's name, address and date of birth. We will also collect your contact email address. We will use this information to do the research or to check your child's records to make sure that the research is being done properly.

Individuals from Alder Hey Children's NHS Foundation Trust, the University of Liverpool and CPRD and regulatory organisations may look at your child's medical and research records to check the accuracy of the research study.

People who do not need to know who you and your child are will not be able to see yours or their name or contact details. Your child's data will have a code number instead.

We will keep all information about you and your child safe and secure.

Once we have finished the study, we will keep the data for 15 years, so we can check the results.

We will write our reports in a way that no-one can work out that your child took part in the study.

## What are my choices about how my child's information is used?

Your child can stop being part of the study at any time, without giving a reason, but we will keep information about your child that we already have.

If you choose for your child to stop taking part in the study, we would like to continue to follow up your child using their electronic health records, and you will still be invited to complete the surveys. If you do not want this to happen you can tell your GP and we will stop.

In some cases, we may need to continue to collect limited information about any side-effects of the study treatment your child may experience. We will only do this where we are required to do so by law.

We need to manage your child's records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you or your child.

## Information sharing for other research

When you agree for your child to take part in a research study, the information about their health and care may be beneficial to researchers running other research studies in this organisation and in other organisations.

These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad.



Your child's information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research, or equivalent standards.

## Where can I find out more about how my information is used?

You can find out more about how we use yours and your child's information:

- at [www.hrs.nhs.uk/information-about-patients](http://www.hrs.nhs.uk/information-about-patients)
- in the Health Research Authority leaflet available from [www.hra.nhs.uk/childdataandresearch](http://www.hra.nhs.uk/childdataandresearch)
- by contacting the Alder Children's Hospital NHS Trust DPO on [info.gov@alderhey.nhs.uk](mailto:info.gov@alderhey.nhs.uk)
- by contacting the University of Liverpool Data Protection Officer (DPO) on [LegalServices@liverpool.ac.uk](mailto:LegalServices@liverpool.ac.uk)
- by contacting the University of Bangor DPO on [info-compliance@bangor.ac.uk](mailto:info-compliance@bangor.ac.uk)
- by contacting the Clinical Practice Research Data Link DPO on [dataprotection@mhra.gov.uk](mailto:dataprotection@mhra.gov.uk)
- by asking your child's GP

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## What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to your GP or practice nurse who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this by contacting your local NHS Patient Advice and Liaison Service (PALS) or equivalent. Your GP practice should be able to provide this information to you.

Every care will be taken in the course of this clinical study. However, in the unlikely event that your child is harmed by taking part in this research project, there are no special compensation arrangements.

If your child is harmed and this is due to someone's negligence, then they may have grounds for a legal action for compensation against the NHS Trust where they are being treated but you may have to pay legal costs. The normal National Health Service complaints procedures should be available to you and your child.

If you wish to raise a complaint on how any research organisation has handled yours or your child's personal data, you can contact the relevant Data Protection Officer who will investigate the matter. If you are not satisfied with their response or believe they are processing your or your child's personal data in a way that is not lawful you can complain to the Information Commissioner's Office.

Thank you for reading this information sheet.  
We hope it has been of interest to you.