

Participant Information sheet for parents

V7.0 30-09-2025

CONTENTS - PART 1

Key information about the study	Page 2
Why has my child been invited to take part?	Page 2
Why are we doing this study?	Page 2
What will we have to do if we take part?	Page 3
Does my child have to take part?	Page 4
Will taking part be confidential?	Page 4
What happens if I change my mind?	Page 5
How will I know which group my child is in?	Page 5
What are the alternatives for treatment?	Page 5
What if I'm worried about my child's asthma?	Page 5
What are the benefits of taking part?	Page 6
What are the risks of taking part?	Page 6
What happens when the study stops?	Page 6
I'm interested in taking part, what do I do next?	Page 7
Information sheet part 2 - Detailed information about the study.	Page 8-11

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** or

filling out this form:

https://bit.ly/ASYMPTOMATIC_EOI_V2



Your child can help us decide the most effective treatment for children who live with asthma.

This leaflet tells you more about the ASYMPTOMATIC study and how to take part.

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

This leaflet is about the study and what taking part involves. Please take your time to read the information carefully and to consider whether or not you wish your child to take part.

Please feel free to discuss the study with your friends and relatives, you can also contact your GP practice or a study paediatrician if you have questions and would like more information. Your GP contact details are on the letter or email you received with this information sheet. The central study number for a study paediatrician is: 07971307807

Taking part is voluntary. If you do not want your child to take part, their usual care will continue as normal.

Key Information about the study

This study is for children who have mild asthma and are aged 6 – 15 years old.

This study will compare the two ways of taking a corticosteroid inhaler and 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”).

Your GP practice thinks that both these ways of taking a corticosteroid inhaler are suitable for your child.

Children in the study can see their GP at any time about their asthma and their GP/asthma nurse can change their inhalers/treatment as needed.

Children take part for one year. There are no extra visits to your GP or hospital and there are no extra tests. You and your child will not need to take time off work or school.

There are questionnaires to complete when you start the study and then again after 4, 8 and 12 months. These take about 20 minutes to complete and you’ll get a £5 voucher each time we send the questionnaires (£20 in total).

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.

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.

Your GP has sent you this information because they think that either way of taking a corticosteroid inhaler would be suitable for your child.

Why are we doing this study?

Preventing asthma attacks is very important.

All children with asthma should be taking an inhaled corticosteroid steroid inhaler as well as their blue reliever inhaler as we know that it can be dangerous to take the blue inhaler alone.

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

continued...Why are we doing this study?

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 this one.

The study will compare two groups:

(1) children taking inhaled corticosteroids every day (daily)

(2) children taking inhaled corticosteroids only when they have asthma symptoms (symptom-driven).

We want to know 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?

Your child will be asked to take their corticosteroid inhaler in one of two ways:

"Daily corticosteroids"

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

"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.

Why are we doing this study?

The study will use your child's health record to collect information about any asthma attacks they might have. You will not need to attend any extra visits to the GP practice or hospital, and there are no extra tests. You will not need to take time off work or school to take part in this study.

You will be asked to 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.

continued...What will we have to do if we take part?

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 access to computers and to the internet if needed.

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.

We will send a £5 Love to Shop gift voucher by email each time there are questionnaires to complete.

The gift voucher will be a code sent to you by email, it 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 sent	£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.

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

Yes. All the 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.

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.

A decision 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?

Your doctor thinks that either group is suitable for your child but neither you nor your child's doctor choose which group they are in.

Instead your GP will use a computer programme to decide which group your child is in 'at random' – you might hear this described as 'randomisation' or 'random allocation', but they all mean the same thing.

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 your child.

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 happens if I am worried about my child's asthma?

If you have any concerns about your child's asthma, at any time, you should contact your GP and arrange an appointment.

Your GP will change your child's asthma treatment if needed.

What are the benefits of taking part?

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 corticosteroids over the course of a year, and spend less time taking their inhalers.

Taking part is an opportunity for you and your child to one day look back and see how you helped develop more effective treatment for children with asthma.

What are the risks of taking part?

The Medicines for Healthcare Regulatory Agency (MHRA) have assessed this to be a low risk study.

If at any time you are worried about your child's asthma your GP will be able to change or add to your child's asthma treatment as 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.

What happens when the study stops?

After taking part in the study your child will return to standard asthma care in discussion with your GP.

When all of the children taking part have completed the study we may present the study results at scientific conferences and publish them in medical journals so that we can explain to the medical community what our research has shown.

The study is scheduled to be completed by 2028 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.

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.

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

After reading this information please let your GP know your decision by choosing one of the following options:

- **Confirm that your child will take part in the study**
- **Book an appointment to discuss the study, with someone at our GP practice or a study doctor, and ask any questions**
- **Decline taking part in the study**

You can let us know your decision by contacting your GP practice or the central study team. Details of how to contact your GP or the central study team are available on the letter or email that you were sent with this information sheet.

Alternatively please use the QR code below or visit https://bit.ly/ASYMPTOMATIC_EOI_V2 to confirm your choice or book an appointment.

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

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



CONTENTS - PART 2

Detailed information about the study	Page 8
How will you collect and use information about my child?	Page 9
What are my choices about how my child's information is used?	Page 9
Information sharing for other research.	Page 10
Where can I find out more about how my information is used?	Page 10
What if there is a problem?	Page 11
How to contact us	Page 11

Part 2. Detailed information about 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, The University of Liverpool, and Bangor University are the joint Data Controllers for this study and will need to use information from you or from your medical records for this research project.

Clinical Practice Research Datalink (CPRD) are data processors and will only use your information in a way approved by the Data Controllers.

Individuals from Alder Hey Children's NHS Foundation Trust, the University of Liverpool, Bangor University 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 your or your child's 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 in accordance with the General Data Protection Regulation (GDPR).

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

Your child's data will be anonymised in any published reports, and no readers will be able to identify that they 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 unless you tell us that you want the information removed.

If you choose for your child to stop taking part in the study, by stopping their treatment, we would still like to continue to follow up your child using their electronic health records, and to ask you to complete the surveys. This information is still important for the study. But, if you do not want this to happen you can tell your GP and we will stop.

Although the risk of side effects is low in this study, if your child did experience any and you decide to stop taking part we may still need to collect limited information about the side-effects from your medical record. We will stop doing this as soon as we have all of the information about the side effect that we are required to report, by law, to the Medicines for Healthcare Regulatory Authority.

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

Information that identifies your child will never be shared for other research purposes. However, anonymised information about your child's 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 anonymous 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 information relating to you and your child:

- in the Health Research Authority leaflet available from <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/>
- by contacting the Alder Children's Hospital NHS Trust Data Protection Officer on info.gov@alderhey.nhs.uk
- by contacting the University of Liverpool Data Protection Officer on LegalServices@liverpool.ac.uk
- by contacting the University of Bangor Data Protection Officer on info-compliance@bangor.ac.uk
- by contacting the Clinical Practice Research Data Link Data Protection Officer on dataprotection@mhra.gov.uk
- by asking your child's GP

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 to protect your child's safety. 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 due to someone's negligence, then they may have grounds for legal action for compensation against the NHS Trust where they are being treated (you may have to pay legal costs).

If you wish to raise a complaint on how any research organisation has handled personal data pertaining to your or your child, you can contact the relevant Data Protection Officer who will investigate the matter.

The details of the Data Protection Officer for each organisation in the study are listed on page 10. 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 (ICO)).

Thank you for reading this information sheet.

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** or request a call back by filling out the form here: https://bit.ly/ASYMPTOMATIC_EOI_V2



Information sheet for children aged 6-11 years

Version 4.0 14-03-2024

This leaflet tells you about the ASYMPTOMATIC study.

This is a study about treating asthma in children.

You and your parents might like to join in this study. This leaflet will help you decide.

Why are we doing the ASYMPTOMATIC study?

We are doing a study to find out the best way for children with asthma to take their corticosteroid inhalers.

You have two inhalers for your asthma.



One is blue.

You use this one when your asthma makes it hard to breathe.



One is brown or orange.

You use this one to stop your asthma from being bad. This is called a **“corticosteroid inhaler”**.

Doctors usually tell children with asthma to use their steroid inhaler every day.

We don't know if all children need to do this.

We want to find out if children can take their corticosteroid inhaler only when their asthma is bad, instead of every day.

Why have you asked me?

We have asked you if you'd like to take part because you have asthma that your doctor thinks is not causing you much trouble at the moment.

If I take part, what will I have to do?

In our study, we will split children with asthma into two groups.

Group 1

Children will take their corticosteroid inhaler every day.

Group 2

Children will take their corticosteroid inhaler only when their asthma is bad.

In both groups we will see how many children have asthma attacks.

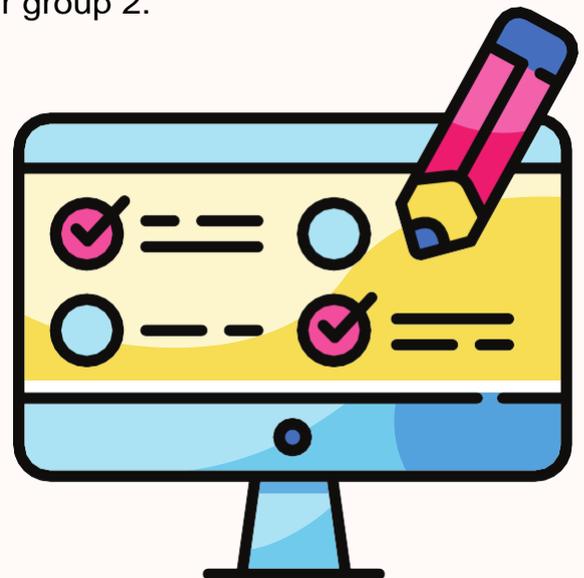
You, your parents or your doctor, won't be able to choose which group you are in. Instead a computer programme chooses. This makes sure that there is a mix of different people in each group. You have the same chance of being in group 1 or group 2.

If you take part you will be in the study for **one year**.

As well as taking your inhaler, as your doctor has asked you to, we will ask you to help your parents fill in some questions about how you are getting on. You could fill these in by yourself if you want to. We will send the questions to your parents four times by email.

Each time it should take no more than 20 minutes to give your answers. We will send you a £5 gift voucher, by email to your parents, each time there are questionnaires to complete.

You will not need to do anything else. You can carry on doing everything as you normally would. This includes going to school or clubs, seeing your friends, and doing activities at home.



15 min



20 min



20 min



20 min

Baseline

4 months

8 months

12 months

Number of questionnaires to fill in.	2	3	3	3
Gift voucher for filling in all questionnaires	£5	£5	£5	£5

Do I have to take part?

You don't have to say yes. No one, including your parents or doctor, will be upset if you don't want to take part.

If you take part and later change your mind, that's OK too. You don't have to tell us why you changed your mind.

Are there any risks to taking part?

The main risk is that we do not yet know if taking your inhaler only on days when your asthma is bad has any effect on the number of asthma attacks that you have.

Your doctor will be able to change your treatment if your asthma is bad.

Will taking part help me?

We cannot promise the study will help you.

But, we hope that doctors will use the results of the study to help them decide how children with asthma should take their steroid inhaler. This might help other children with asthma, in the future.

Who checked that the study was ok to do?

The ASYMPTOMATIC Study has been checked by a group of people called a Research Ethics Committee.

They are not part of the study but make sure that the research is fair and safe to do.

Who is leading the study?

Lots of people are involved in the study including your GP.

There are also other doctors and scientists who will help to run the study and look at the results. You will not have to meet them and they will only see information that doesn't have your name on.



The main doctor is called Ian. He is a doctor who treats lots of children with asthma.



He works in a city called Liverpool, in a hospital called Alder Hey. It is a hospital that only looks after children.

In the team doing the study there are also some children with asthma and their parents. They are helping us with the study and making sure we are doing the study right.

What do I do if I have questions?

Please talk to your parents about any questions you might have, they can also arrange to talk to your doctor if they need to.

Thank you for reading this leaflet about the **ASYMPTOMATIC** study.