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Do children with mild asthma need to take inhaled steroids everyday or only as when they need them?

Submission date
15/06/2021

Recruitment status
No longer recruiting

Registration date
08/10/2021

Overall study status
Ongoing

Last Edited
27/01/2025

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Asthma is the commonest long-term disease in children in the UK. It causes cough and difficulty breathing. The main treatment for asthma is a preventer inhaler, containing steroids, which prevents irritation of the airways. For many years we have advised children with asthma to use their preventer inhaler every day. However, new guidelines recommend that taking a preventer inhaler every day might not be required in all children. These guidelines are based on results of studies in adults, and some teenagers, with asthma. But, asthma in adults is different from asthma in children and so we need to do the ASYMPTOMATIC trial to provide evidence on whether taking a preventer inhaler only when a child, with mild asthma, has symptoms is as effective as taking it every day.
We want to find out whether there is a difference between the two approaches in terms the chances of having an asthma attack, asthma symptoms, hospital admissions, and overall quality of life.

Who can participate?
The study will involve around 250 GP practices across the UK. Children and young people, with mild asthma, may participate.

What does the study involve?
Participants will be randomly assigned to one of two different approaches to using the preventer inhaler, for 12 months:
1. Taking their inhaler every day
2. Taking their inhaler only when they have symptoms of asthma.
To find out about quality of life and asthma symptoms we will ask participants to complete short questionnaires online at baseline, 4, 8, and 12 months.

What are the possible benefits and risks of participating?
Benefits - At present, the normal practice in preventing asthma attacks is to take steroid inhalers in a “Daily” manner. We know this approach works at reducing asthma attacks.
However, we do not know if taking steroids every day is necessary for all children with mild

asthma. If children could take inhaled steroids only when they needed them, without increasing the risk of asthma attacks, this would have advantages. They would have a smaller amount of steroid over the course of a year and spend less time taking their inhalers.
Risks - There will always be a member of the research team that you can phone if you are concerned about anything or for advice.
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.
Confidentiality will be ensured at all times and you and your child will not be identified in any publication.

Where is the study run from?
Alderhey NHS Trust (UK)

When is the study starting and how long is it expected to run for?
September 2020 to June 2026

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
297649

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 297649, CPMS 50134

Study information

Scientific Title
Assessing SYmptom-driven versus Maintenance Preventer Therapy for the Outpatient Management of AsThma In Children (ASYMPTOMATIC): A non-inferiority, pragmatic, randomised controlled trial using routinely collected outcome data

Acronym
ASYMPTOMATIC

Study objectives
This trial aims to examine whether children with mild asthma should use ICS regularly or only when they have symptoms.
The primary objective of this trial is to identify whether in children (aged 6 - 16 years) with mild asthma, symptom-driven use of ICS is non-inferior to daily maintenance ICS on the risk of asthma attacks requiring oral corticosteroid (OCS).
The primary economic objective is to estimate the cost-effectiveness (incremental cost per quality-adjusted life year, QALY gained) of symptom-driven use of ICS.
Secondary objectives are to compare symptom-driven ICS with maintenance ICS with regards to:
1. Asthma control
2. Use of unscheduled health care
3. Hospitalisations
4. HRQoL

5. Treatment failure
6. Mortality
7. Cumulative dose of ICS over the 12 month treatment period

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild asthma

Interventions
The ASYMPTOMATIC trial is a pragmatic non-inferiority open-label RCT with a 1:1 participant allocation ratio, in general practices across the UK that are registered with the Clinical Practice Research Datalink (CPRD). Data will be obtained from electronic health records (EHR) and approved linked datasets, using routinely collected health information, direct patient report using electronic case report form – (IRSP), and an eCRF for Investigators (IRSP).
We will compare two strategies for using ICS, given over a 52-week treatment period:
Arm 1: Maintenance ICS
IMP: Beclometasone Dipropionate, Fluticasone propionate and Budesonide
Dose: 200 mcg/24 hours, Budesonide equivalent, for 6 - 11-year-olds, 400 mcg/24hours, Budesonide equivalent, for 12 - 16-year-olds daily. (inhalded)
Arm 2: Symptom driven ICS
IMP: Beclometasone Dipropionate, Fluticasone propionate and Budesonide
Dose: 200 mcg/24 hours, Budesonide equivalent, for 6 - 11-year-olds, 400 mcg/24hours, Budesonide equivalent, for 12 - 16-year-olds, on days where short acting beta agonist is used.

The primary outcome is the occurrence of at least one asthma attack requiring treatment with OCS over the 12 month treatment/follow up period. Secondary outcomes will be asthma control, HRQoL, treatment failure, unscheduled healthcare utilisation, cumulative dose of ICS in the last 12 months, mortality and hospitalisations. We will also undertake a cost-effectiveness analysis of the two approaches.

The ICS (beclomethasone, fluticasone, or budesonide 200 mcg/24 hours for 6-11 year olds, 400 mcg/24hours for 12 - 16-year-olds) will be chosen by the GP, in line with their local processes, prior to randomisation and their choice of inhaler recorded in the randomisation system. ICS will be administered using a metered dose inhaler (MDI) and, if required, spacer device. A dry powder inhaler may be used for children aged 12 years and over.

Participants will be randomised to Arm 1 or Arm 2 and will receive treatment in line with the allocated arm for 12 months from randomisation. Participants will be followed up, at intervals over the 12 month treatment period, using the EHR and patient-reported outcome data.

We aim to minimise participant attrition by using routine EHR data for follow-up outcomes without the need for additional trial-specific visits.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Beclometasone dipropionate, fluticasone propionate, budesonide

Primary outcome(s)
1. Number of asthma attacks requiring treatment with OCS in the 12-months after randomisation. Information on this outcome will be obtained from prescription records and through linkage with Hospital Episode Statistic (HES) data.
2. Cost per QALY gained (ICER) over the 12 month treatment/follow up period measured using:
2.1. CHU-9D questionnaire responses at baseline, 4, 8- and 12-months
2.3. Resource use from HES and CPRD data at the end of the trial
2.4. For utilities: application of UK tariff scores
2.5. For QALYs: area under the utility-time curve
2.6. For costs: sum-product of all measured items of resource use and their respective NHS unit costs
ICER calculated as the difference in total costs between intervention groups, divided by the difference in QALYs.

Key secondary outcome(s))
At 4, 8 and 12 months after randomisation
1. Asthma control measured using Asthma Control Test (ACT)
2. Participant adherence to the intervention (adherence questionnaire)
3. Health utility (CHU9D tool)
4. Cumulative dose of ICS over the 12 month treatment period (estimated from the number of ICS inhalers prescribed, as indicated from prescription records)
5. Treatment failure (i.e. when LABA or LTRA additional preventer therapies were prescribed, as determined from prescription records)
6. Hospitalisation and mortality will be identified from linked HES data
7. Serious Adverse Events (SAEs). SAEs will be reviewed by the CI and Suspected Unexpected Serious Adverse Reactions (SUSARs) reported accordingly by GPs

Completion date
01/06/2026

Eligibility

Key inclusion criteria
1. Aged 6 - 15 years inclusive
2. Mild asthma, including children with a new diagnosis.

3. At least one relevant (for asthma) prescription of short acting beta agonists (SABA) or inhaled corticosteroids (ICS) in the last 12 months (including new diagnoses)
4. Written and informed consent and assent from the participant's legal representative and participant respectively (for participants under 16 years of age)and agreement of the participant to comply with the requirements of the trial
5. Ability of the parent, and young person where appropriate, to complete patient reported outcomes in English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
15 years

Sex
All

Key exclusion criteria
1. Hospitalised for asthma in the last 12 months (this does not include children who have attended the ED but not been admitted)
2. Three or more asthma attacks treated with oral corticosteroids in the last 12 months
3. Significant respiratory comorbidity including cystic fibrosis, immunodeficiency or interstitial lung disease
4. Prescribed, or taking, any of the following at the time of randomisation: montelukast, long acting beta-agonist whether in combination with ICS or as a separate inhaler, azithromycin (given prophylactically). Patients who have previously received these treatments but who are no longer receiving them at the time of randomisation i.e. treatment has been stepped down, are not excluded.

Date of first enrolment
01/07/2021

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR CRN North East and North Cumbria
Regent Point
Regent Farm Road
Gosforth
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United Kingdom
NE3 3HD

Study participating centre
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Sponsor information

Organisation
Alder Hey Children's NHS Foundation Trust

ROR
https://ror.org/00p18zw56

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes