ISRCTN31849868 https://doi.org/10.1186/ISRCTN31849868

Can we reduce asthma attacks in children using spirometry measurements and symptoms?

Submission date
27/06/2022

Recruitment status
No longer recruiting

Registration date
01/07/2022

Overall study status
Ongoing

Last Edited
18/06/2025

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Asthma affects 1.1 million children in the UK. Asthma attacks are frightening for the child and their family and can be fatal. A child has an asthma attack every 2.5 minutes, and one-in-10 of these children is admitted to hospital. Current guidelines say that recent asthma control (symptoms) should guide treatment choices to prevent attacks. What is needed is a reliable and evidence-based test, which can be used alongside asthma control (symptoms) to guide treatment and reduce the number of asthma attacks.

Spirometry is a simple breathing test that does not change over time when asthma is controlled. Spirometry could be a very useful test to monitor asthma because it measures lung function, i.e. how the lungs are working. To do spirometry, children take a big breath in and breathe out through a tube as hard as they can. The amount of air they can breathe out in the first second is called the FEV1 (forced expiratory volume in 1 second). Currently, doctors disagree about how to best use spirometry to monitor asthma because of a lack of research evidence and conflicting guidance from experts. We know that only ~25% of hospital doctors in the UK use spirometry regularly in their asthma clinics. Our recent research shows that a 10% fall in FEV1 over a 3-month period is followed by a 28% increased risk of an asthma attack in the next 3 months. We still do not know why using spirometry to guide treatment may lead to reduced attacks.

This research proposal will build on our previous research findings to answer the question “In children with asthma does spirometry and symptom-guided treatment, compared to symptom-guided treatment alone, reduce the number of asthma attacks?” In this study, we also will further explore the links between treatment guided by spirometry and the risk of attacks.

Who can participate?
Children aged between 6 and 15 years old who have asthma and have had an asthma attack in the last year

What does the study involve?
Everyone that takes part will be put into one of two groups and has an equal chance of getting treatment in group 1 (treatment guided by spirometry plus asthma control (symptoms)) or group 2 (treatment guided by asthma control (symptoms) alone). All children will have

spirometry measured at every visit. Asthma control (symptoms) and other asthma details will be gathered from questionnaires. A computer programme will guide treatment decisions based on symptom score, current treatment and also, in group 1, spirometry measurements. At 3-month intervals over a year, children will meet the research team, complete the symptom questionnaire, and spirometry, and have their treatment changed according to spirometry and asthma control (symptoms), or asthma control (symptoms) alone. We will measure asthma attacks and other outcomes over 12 months.

What are the possible benefits and risks of participating?
Families will be informed of the possible benefits and disadvantages of taking part by means of information leaflets, discussion with local research nurses and the asthma team. All participants may benefit because they have a more regular follow-up for their asthma. Participants who are randomised to the treatment guided by spirometry plus asthma control may benefit because the intervention may reduce the risk of exacerbations. The policies of recommending treatment based on asthma control (symptoms) only and based on spirometry plus asthma control (symptoms) are both used routinely within the NHS. We do not anticipate that participants will run additional risks by participating in SPIROMAC. Parent/carer(s) of children will sign a consent form approved by the Ethics Committee. Children or families who are not willing to be randomised will not be recruited.

Where is the study run from?
Royal Aberdeen Children's Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2021 to December 2026

Who is funding the study?
National Institute for Health Research (NIHR) Efficacy and Mechanisms Evaluation (EME) Programme (UK)

Who is the main contact?
Nicole Sergenson (UK)
nicole.sergenson@abdn.ac.uk

Study website
https://w3.abdn.ac.uk/hsru/SPIROMAC/Public/Public/index.cshtml

Contact information

Type(s)
Scientific

Contact name
Ms Nicole Sergenson

Contact details
CHaRT
Health Services Research Unit
Health Sciences Building
Foresterhill
Aberdeen

United Kingdom
AB25 2ZD
+44 (0)1224 438089
nicole.sergenson@abdn.ac.uk

Type(s)
Principal Investigator

Contact name
Prof Steve Turner

ORCID ID
https://orcid.org/0000-0001-8393-5060

Contact details
Child Health
Royal Aberdeen Children's Hospital
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD
+44 (0)1224438470
s.w.turner@abdn.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
306946

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 53202, IRAS 306946

Study information

Scientific Title
SPIROmetry to manage asthma in children (SPIROMAC)

Acronym
SPIROMAC

Study objectives
We hypothesise that asthma treatment guided by spirometry will improve flow and volumes and that this will lead to reduced asthma attacks. SPIROMAC will therefore determine whether the spirometry-guided treatment reduces attacks by achieving one or more of the following:

1. Increased spirometry measurement as evidenced by improved airway flow (FEV1)
2. Increased spirometry measurement as evidenced by improved lung volume (FVC)
3. Reduced eosinophilic airway inflammation, as evidenced by a fractional exhaled nitric oxide (FeNO) test. The mechanistic aim has eosinophilic airway inflammation as an intermediary on the mechanistic pathway we will explore between treatment guided by spirometry plus symptoms (the effector) and reduced asthma attacks (the outcome). Eosinophilic inflammation may be relevant to attacks independently of lung function (as evidenced by FEV1 and FVC). FeNO is not part of the SPIROMAC treatment algorithm and is being measured to give this mechanistic insight.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/05/2022, West Midlands – Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)207 104 8010; blackcountry.rec@hra.nhs.uk), ref: 22/WM/0097

Study design
Randomized interventional

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Asthma

Interventions
We will invite eligible children to take part in our study. We hope to be able to recruit children at up to 40 hospital-based asthma clinics and primary care practices across the UK.
We aim to recruit 550 children aged 6-15 years with asthma who have had an asthma attack in the last year.
There will be five study visits, the first one will be the recruitment visit. There will then be four follow-up study visits, approximately every three months.
At the first appointment with the research team, permission to take part in the study will be obtained from the parent/carer and from the child.

Children will be put into one of two groups (randomised) and have an equal chance of getting treatment in group 1 (treatment guided by spirometry plus asthma control (symptoms)) or group 2 (treatment guided by asthma control alone).

At the first visit all children will:
1. Answer some questions about themselves and their asthma
2. Have spirometry measured
3. Have their height and weight measured
4. Complete a questionnaire about asthma control (symptoms)
5. Complete a questionnaire about their quality of life
6. Have another breathing test that measures fractional exhaled nitric oxide (FeNO)

A computer programme will guide treatment decisions based:
1. Group 1, on their asthma control (symptoms), their current treatment and spirometry measurements.
2. Group 2, on their asthma control (symptoms) and their current treatment

At the end of the first visit, we will give children a small device (called a smart inhaler) that will fit on their asthma preventer inhaler to measure how frequently they take their inhaler.
We will see children every three months for the next year.

At each of the follow-up visits, children will:
1. Be asked to tell us if they have had any asthma attacks since their last visit
2. Have spirometry measured
3. Have their height measured
4. Complete a questionnaire about asthma control (symptoms)
5. Have another breathing test that measures fractional exhaled nitric oxide (FeNO)
6. Have adherence data downloaded from their smart inhaler

As at the first visit, a computer programme will guide treatment decisions based:
1. Group 1, on their asthma control (symptoms), their current treatment, adherence to their preventer inhaler and spirometry measurements
2. Group 2, on their asthma control (symptoms), their current treatment and adherence to their preventer inhaler

At their last follow-up visit (at 12 months) we will ask them to complete a quality of life questionnaire.
We will then compare the number of asthma attacks between the two groups over the 12-month follow-up period.

Intervention Type
Other

Primary outcome measure
Asthma attacks in children with spirometry plus asthma control (symptoms) compared with asthma control (symptoms) alone measured using participant-reported asthma attacks that require treatment with 1-7 days of oral corticosteroids and/or intravenous corticosteroids up to 12 months post-randomisation

Secondary outcome measures

1. Efficacy in children receiving spirometry plus asthma control (symptoms) compared with asthma control (symptoms):
1.1. Any asthma attack measured using participant-reported asthma attacks up to 12 months – data collected at each follow-up, 3, 6, 9, 12 months
1.2. Time to a first asthma attack measured using participant reported first asthma attack up to 12 months – data collected at each follow-up, 3, 6, 9, 12 months
1.3. Health-related quality of life measured using Paediatric Asthma QoL Questionnaire at 12 months only
1.4. Asthma control (symptoms) measured using Asthma Control Test/Children's Asthma Control Test up to 12 months – data collected at each follow-up, 3, 6, 9, 12 months
1.5. Adverse events measured using participant-reported events up to 12 months
1.6 Dose of inhaled corticosteroids measured using participant reported dose of inhaled corticosteroid up to 12 months

2. Mechanism of action in children receiving spirometry plus asthma control (symptoms) compared with asthma control (symptoms) alone:
2.1. Airflow (FEV1) measured using spirometry up to 12 months – data collected at baseline and each follow-up, 3, 6, 9, 12 months
2.2. Lung volume (FVC) measured using spirometry up to 12 months – data collected at baseline and each follow-up, 3, 6, 9, 12 months
2.3. Eosinophilic airway inflammation (fractional exhaled nitric oxide, FeNO) measured using the FeNO test up to 12 months – data collected at baseline and each follow-up, 3, 6, 9, 12 months

Overall study start date
01/08/2021

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Aged 6 to 15 years old
2. Asthma diagnosis confirmed by a doctor or a respiratory/asthma specialist nurse (or Read code for asthma if recruited in primary care)
3. Patient/parent reported-asthma attack treated with at least one course of oral corticosteroids in the 12 months prior to recruitment
4. Be able to perform spirometry
5. Be able to understand written/spoken English

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
Planned Sample Size: 550; UK Sample Size: 550

Key exclusion criteria
1. Not being able to perform spirometry satisfactorily
2. Presence of another chronic respiratory condition (e.g. cystic fibrosis)
3. Current treatment with maintenance oral steroids and biologicals (we cannot provide standardised step-up/down treatment options)

Date of first enrolment
01/10/2022

Date of final enrolment
12/06/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Study participating centre
Alder Hey Hospital
Eaton Road
West Derby
Liverpool
United Kingdom
L12 2AP

Study participating centre

Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University of Aberdeen

Sponsor details
Regent Walk
Aberdeen
Scotland
United Kingdom
AB24 3FX
+44 (0)1224437221
researchgovernance@abdn.ac.uk

Sponsor type
University/education

Website
http://www.abdn.ac.uk/

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR129819

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

Publication and dissemination plan
1. Planned publication in a high-impact peer-reviewed journal
2. Conference presentation
3. Publication on website
4. Other publication

Intention to publish date
30/06/2026

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No