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Prescription Alerts for Reliever inhalers in Children (PARC) project

Submission date
15/03/2024

Recruitment status
Recruiting

Registration date
04/07/2024

Overall study status
Ongoing

Last Edited
26/07/2024

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
Many children and teenagers have asthma; a long-term lung condition causing wheezing and breathlessness. Severe asthma attacks may need hospital treatment and can be life-threatening. Two types of inhalers are used to treat asthma: relievers and preventers. Children using high numbers of reliever inhalers are more likely to have severe asthma attacks. It has therefore been recommended that these children should have an urgent check-up. This does not yet routinely happen. This study aims to determine whether children (aged 1-17 years) prescribed 7 or more reliever inhalers in the past year invited to an enhanced nurse-led check-up will have fewer asthma attacks in the following year.

Who can participate?
Children aged 1-17 years old who have been prescribed 7 or more reliever inhalers in the past year

What does the study involve?
General practices across the Wessex and Thames Valley regions will randomly be divided into two groups:
1. Practices offering enhanced asthma check-ups (intervention practices).
2. Practices providing usual asthma care (control practices).

Practices will be asked to identify children aged 1-17 years who have been prescribed 7 or more reliever inhalers in the past year. In intervention practices, these children will be invited for an asthma check-up. This will be undertaken by a specially trained general practice nurse. At the check-up, the team will explore reasons for poor asthma control including symptom triggers, prescribed asthma treatment and whether treatments are taken as prescribed. The children's inhaler techniques will also be checked and families will be provided with an asthma action plan.

At the end of the project, the number of severe asthma attacks in a year in children from intervention and usual care practices will be compared. The study will also evaluate the cost-effectiveness of providing enhanced check-ups to children prescribed high numbers of reliever

inhalers and will talk to some children, their parents and health professionals about their experience of the check-up. This will help with introducing them into routine practice if they prove effective.

What are the possible benefits and risks of participating?
Taking part in this project may improve participants' asthma control and reduce their chance of having asthma attacks in the future. It may also improve their quality of life as asthma can affect people's sleep and ability to take part in activities e.g. sports. Their participation will also help to improve our understanding of how to manage asthma in children and young people and therefore, may benefit others. If participants attend a check-up, they will be given a £5 voucher as a thank-you for their time.

There are minimal risks associated with taking part in this project. The check-up is similar to a standard annual asthma check-up but will be longer and more detailed. No new medications are being tested and no tests will be performed.

Where is the study run from?
University Hospital Southampton NHS Foundation Trust

When is the study starting and how long is it expected to run for?
May 2022 to January 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) programme

Who is the main contact?
Dr Anna Selby, parc@soton.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
332076

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 60369, IRAS 332076

Study information

Scientific Title
Reducing severe asthma exacerbations by using prescription alerts for excessive reliever inhaler use to target high-risk children: a randomised controlled trial

Acronym
PARC

Study objectives
Targeted and enhanced asthma/wheeze reviews in high-risk children will prevent severe asthma /wheeze attacks and are cost-effective

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/03/2024, West of Scotland Research Ethics Service (Research Ethics, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 314 0213; WoSREC5@ggc.scot.nhs.uk), ref: 24/WS/004

Study design
Parallel-group cluster-randomized wait-list controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice, Home, Hospital, Medical and other records, Other therapist office, Telephone

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
Paediatric asthma

Interventions
This is a parallel-group, cluster-randomised controlled trial with a waiting-list control design.

General practices across Hampshire, the Isle of Wight and the Thames Valley region will act as participant identification centres (PICs) and be randomised to intervention and control arms. Intervention practices will perform searches every 3 months for 12 months to identify children prescribed 7 or more short-acting beta-agonist (SABA) reliever inhalers in the previous 12 months.

Children who meet the study inclusion criteria will be offered an enhanced asthma review. This will be 30 minutes in duration and will be undertaken by a specially trained primary care nurse at one of the following locations:
• The Clinical Research Facility (CRF) at University Hospital Southampton NHS Foundation Trust (UHS).
• Research hubs within the Wessex Clinical Research Network (CRN).
• Research buses operated by the Wessex CRN.
• The David Hide Asthma and Allergy Research Centre, St Mary's Hospital, Newport, Isle of Wight.
• The Royal Berkshire Hospital, Reading.
• General practices with clinic room space.
Home visits/virtual reviews will also be offered to families who would not otherwise be able to take part in the project.

In accordance with British Thoracic Society guidelines and The National Asthma Care Bundle, asthma reviews will cover the following areas:
- Patient/carer's understanding of what asthma is, what the symptoms are and how it is treated.
- Current symptom control including frequency of reliever inhaler use, number of attacks/ED attendances/courses of oral corticosteroids in the past year. The asthma control test/children's asthma control test will be completed.
- Symptom triggers/environmental factors e.g. pet and smoke exposure.
- Other health problems that may affect asthma control e.g. allergic rhinitis and obesity.
- Asthma treatment including adherence and inhaler technique.
- Psychosocial factors e.g. stress at home/school and lack of engagement with health care.
- Education and supported self-management including provision of an asthma action plan.

Participants/their parents will be contacted via telephone call approximately 4-8 weeks after their asthma review to check progress with their action plan and ensure that further follow-up by the participant's GP is arranged if necessary.

Control practices will perform searches in the same way as intervention practices, but they will start them 12 months later. The same qualifying period will be used to allow a controlled comparison. For example, for intervention practices starting screening on 01/01/2024, the qualifying period will be the previous 12 months (01/01/2023 to 31/12/2023). Control practices will start screening 12 months later (01/01/2025) but will use the same qualifying period ending 12 months earlier (01/01/2023 to 31/12/2023). Children from control practices who have 7 or more SABA inhaler prescriptions during the qualifying period will be offered an asthma review once outcome data has been collected. The above approach to recruitment has been chosen to

ensure that data on SABA inhaler prescriptions and follow-up data are collected during the same time period in participants from intervention and control practices.
Semi-structured interviews with a selection of participants/their parents in the intervention group will be undertaken approximately one month after their follow-up phone call. The aim of these is to seek an in-depth understanding of families' perception of the intervention and identify facilitators and barriers to implementation.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Number of severe asthma attacks measured using data collected from medical records during the 12 months following the asthma review (intervention group), or during the 12 months before the asthma review (control group)

Secondary outcome measures
The following secondary outcomes will be measured using data collected from medical records during the 12 months following the asthma review (intervention group), or the 12 months before the asthma review (control group):
1. Number of SABA inhalers prescribed
2. Asthma treatment including inhaled corticosteroid dose
3. Number of hospital admissions due to asthma
4. Asthma-related health care visits in primary and secondary care (including ED attendances).

Health economic evaluation:
Healthcare costs and benefits will be compared in the intervention and control groups. This will cover the cost of the intervention, asthma medications, scheduled and unscheduled asthma-related primary care visits, asthma-related ED visits, inpatient care and outpatient hospital care.

Process evaluation:
1. The views of 20-30 parents and 10-15 young people (aged 12 or more) from the intervention arm will be collected approximately one month after their involvement in the project
2. The views of 10-15 healthcare professionals from intervention practices will be collected at the end of the practice's involvement in the project

Overall study start date
01/05/2022

Completion date
31/01/2027

Eligibility

Key inclusion criteria
1. Children aged 1-17 years old
2. 7 or more prescriptions of SABA inhalers e.g. salbutamol during the qualifying period

(previous 12 months for the intervention group, 24-12 months previously for the control group)
3. Informed consent from parent/guardian/participant with assent from participant where appropriate

(Children do not need to have a recorded diagnosis of asthma to be eligible to participate in the project)

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
Planned Sample Size: 614; UK Sample Size: 614

Key exclusion criteria
1. Other (in addition to asthma) long-term respiratory condition e.g. cystic fibrosis.
2. Enrolled in another interventional research study.
3. Participant or parent/guardian unable to communicate sufficiently (with an interpreter where available) to complete consent forms and have an asthma review.

Date of first enrolment
01/07/2024

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southampton General Hospital
Tremona Road

Southampton
United Kingdom
SO16 6YD

Study participating centre
St Marys Hospital
Parkhurst Road
Newport
United Kingdom
PO30 5TG

Study participating centre
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

Sponsor details
R&D Department, Duthie Building, MP 138, Tremona Road
Southampton
United Kingdom
SO16 6YD
+44 (0)2381205044
sponsor@uhs.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.uhs.nhs.uk/

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Our publication and dissemination plans are as follows:
1. Planned publication in a high-impact peer-reviewed medical journal
2. Presentations at relevant conferences e.g. the Primary Care Respiratory Society (PCRS) and Royal College of Paediatrics and Child Health (RCPCH) annual meetings.
3. A training package for primary care nurses to enable the intervention to be delivered.
4. A lay summary accessible via the Asthma+ Lung UK website.

Intention to publish date
01/01/2028

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?
Participant information sheet	version 1.1	30/01/2024	17/05/2024	No	Yes
Participant information sheet	version 1.1	30/01/2024	17/05/2024	No	Yes
Participant information sheet	version 1.1	30/01/2024	17/05/2024	No	Yes
Participant information sheet	version 1.1	31/01/2024	17/05/2024	No	Yes

Participant information sheet	version 1.2	03/05/2024	26/07/2024	No	Yes
Participant information sheet	version 1.2	03/05/2024	26/07/2024	No	Yes
Participant information sheet	version 1.2	03/05/2024	26/07/2024	No	Yes