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Using high flow moist oxygen early to treat acute severe asthma in children

Submission date 16/02/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 20/02/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 16/03/2026	**Condition category** Respiratory	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Asthma is common in children, and many come to hospital with severe attacks. Most children get better after highdose inhaler treatment, but some do not and may need medicines given into a vein, which can be unpleasant. The study aims to find out whether giving high flow humidified oxygen early helps children recover more quickly and reduces the need for intravenous therapy.

Who can participate?
Children aged 2 to 18 years who come to hospital with a severe asthma attack and still have breathing problems after receiving usual highdose inhaler treatment may be able to take part. Children will not be able to join if they have pneumonia, very severe lifethreatening asthma, reduced consciousness, conditions that make high flow oxygen unsafe, other major illnesses, or if they have taken part in this study before.

What does the study involve?
Children who join the study will receive either early high flow humidified oxygen or usual care. The treatment will start straight away because asthma attacks need urgent care. There are no extra blood tests. Families will be asked to give consent for the use of their child's data once the emergency has passed, usually the next working day. The study team will compare how quickly children recover, whether they need intravenous treatment, how long they stay in hospital, and how they feel during recovery.

What are the possible benefits and risks of participating?
Children receiving early high flow oxygen may recover more quickly and may be less likely to need intravenous treatment. High flow oxygen is already used for other breathing problems in children and has a good safety record. Risks are low but, as with any treatment, there may be minor discomfort or side effects.

Where is the study run from?
The study is being carried out in hospitals across England and Scotland, including Brighton, Canterbury, Middlesbrough, Edinburgh, Oxford, Blackburn, Dartford, Salisbury and StokeonTrent.

When is the study starting and how long is it expected to run for?
The first participants are expected to join the study on 16 March 2026. Recruitment is planned to continue until 31 December 2027, with the whole study expected to finish by 30 June 2028

Who is funding the study?
The study is funded by the National Institute for Health and Care Research (NIHR).

Who is the main contact?
Dr Akshat Kapur, akshat.kapur@nhs.net
Brighton and Sussex Clinical Trials Unit, CTU-HOPSA@bsms.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Dr Akshat Kapur

ORCID ID
https://orcid.org/0000-0003-1772-9300

Contact details
Royal Alexandra Children's Hospital
Brighton
United Kingdom
BN2 5BE
+44 1273696955
akshat.kapur@nhs.net

Type(s)
Principal investigator, Scientific

Contact name
Prof Paul Seddon

ORCID ID
https://orcid.org/0000-0003-2136-958X

Contact details
Royal Alexandra Children's Hospital
Brighton
United Kingdom
BN2 5BE
+44 7714777361
paul.seddon@nhs.net

Type(s)
Scientific, Public

Contact name
Dr Hector Rojas Anaya

ORCID ID
https://orcid.org/0000-0001-7817-8720

Contact details
Brghton and Sussex Clinical Trials Unit
Brighton
United Kingdom
BN1 9PH
+44 1273 641469
CTU-HOPSA@bsms.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
344459

Central Portfolio Management System (CPMS)
62634

National Institute for Health and Care Research (NIHR)
208869

Study information

Scientific Title
High flow humidified oxygen as an early intervention in children with acute severe asthma: a randomised controlled trial (High flow humidified oxygen in paediatric severe asthma)

Acronym
HOPSA

Study objectives
To determine whether early HiFlo (commenced within 4 hours of starting high dose inhaled “burst” therapy) reduces the need for escalation to intravenous bronchodilator therapy.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/12/2025, Nottingham Research Ethics Committee 1 (2 Redman Place, London, E20 1JQ, United Kingdom; +44 207 104 8115; Nottingham1.rec@hra.nhs.uk), ref: 25/EM/0236

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Acute severe asthma in children

Interventions
Eligible children will be randomised using an online software application to the HiFlo or usual care arm. This will be performed by clinical staff using a computer desktop link and administered by the Clinical Trials Unit, as successfully piloted in the feasibility study.
The randomisation list will be pre-generated by the Brighton and Sussex Clinical Trials Unit and uploaded to the randomisation system. The list will be block randomised with random block sizes, and stratified by age (2-4 years, 5-10 years, 11-18 years) and severity at study entry (oxygen saturation less than 92%, 92-94%).
Randomised treatment will apply during the hospital admission, and follow-up will be for 48 hours after discharge from hospital (and only to measure the outcome of Readmission within 48 hours)

HiFlo (Intervention) arm
Children randomised to the HiFlo arm will be commenced on HiFlo by the clinical team immediately after randomisation (within a window of 30 minutes), and flow will be gradually increased to a target flow determined by body weight, using the targets published in the FIRST-ABC Study [36]. Inspired oxygen concentration will be adjusted to the minimum required to maintain oxygen saturation (by pulse oximeter) at 92% or higher. Other treatment for acute asthma will continue during HiFlo therapy. Inhaled bronchodilators will be administered via in-line vibrating mesh nebuliser (Aerogen Ltd), since this is the only effective way of administering inhaled bronchodilator on HiFlo. Children who have not already received an oral corticosteroid dose during burst therapy will receive a single dose of prednisolone or dexamethasone (according to local guidelines) at randomisation – further doses of oral corticosteroids during admission will be at the discretion of the clinical team. All treatment options will be allowed as clinically indicated, and further escalations of treatment will occur as judged necessary by the treating clinical team. These can include intravenous bronchodilators (magnesium, salbutamol, aminophylline), and respiratory support with continuous positive airway pressure (CPAP), bi-level airway pressure (BiPAP) or invasive ventilation.
Once the child's condition stabilises, HiFlo will be weaned according to clear guidelines based on those used in the FIRST-ABC study [36]. In brief, clinicians will be encouraged to reduce flow will once the inspired oxygen required is below 40%, and to discontinue HiFlo once below 30%. Once HiFlo is discontinued, inhaled bronchodilator therapy will continue by metered dose inhaler and spacer or by nebuliser. As the child improves, the frequency of inhaled bronchodilator doses will

be gradually tapered until the point of clinical readiness for discharge is reached. This is defined as no longer requiring additional oxygen or respiratory support, and not requiring inhaled bronchodilators more often than 4-hourly.
Below is the weight banded starting flow rate of Hiflo and weaning flow rate we will use in our study adapted from the First ABC study. Active weaning of Hiflo in children with reduced respiratory distress is really important and we will provide adequate training for it.

Weight (kg) ≤12 13-15 16-30 31-50 >50
Starting flow rate 2L/kg/min 25-30L/min 35L/min 40L/min 50L/min
Weaning flow rate 1L/kg/min 13-15L/min 18L/min 20L/min 25L/min

During administration of inhaled bronchodilators on HiFlo (in-line mesh nebulisation via Aerogen Solo device) Hiflo should be reduced to weaning flow rate as in the table. If already on weaning flow rate, then no adjustment is needed. Once Hiflo stops, standard inhaled or nebulised bronchodilators will be administered as per usual protocol for the unit.

Usual care arm
Children randomised to the usual care arm will continue with treatment for acute asthma as indicated by local procedures and clinical assessment. Inhaled bronchodilator therapy will continue as required according to clinical assessment, and may be administered by metered dose inhaler and spacer or by nebuliser. Children who have not already received an oral corticosteroid dose during burst therapy will receive a single dose of prednisolone or dexamethasone (according to local guidelines) at randomisation – further doses of oral corticosteroids during admission will be at the discretion of the clinical team. All treatment options will be allowed as clinically indicated, and further escalations of treatment will occur as judged necessary by the treating clinical team. These may include intravenous bronchodilators (magnesium, salbutamol, aminophylline), and respiratory support with continuous positive airway pressure (CPAP), bi-level airway pressure (BiPAP) or invasive ventilation. Use of HiFlo as an escalation is permitted, but with the stipulation that starting HiFlo should not be the first escalation of therapy – this corresponds to current clinical practice. Oral corticosteroid therapy will be administered according to local practice and clinical assessment.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Escalation to intravenous therapy during admission measured using Binary yes/no at Recorded at discharge from hospital

Key secondary outcome(s)
1. Deterioration measured using National Paediatric Early Warning Score (NPEWS) and Respiratory subset Score at 2 and 4 hours

2. Asthma Severity measured using Asthma Severity Score at 2 and 4 hours

3. Respiratory rate measured using Breaths per minute at 2 hours

4. Quality of Recovery measured using Quality of Recovery Score (QoR15) at 24 hours

5. Treatment Acceptability measured using Treatment Acceptability Score at 24 hours

6. Duration of hospital admission measured using Hours at Discharge

7. Readmission to hospital due to acute asthma within 48 hours measured using Binary yes/no at 48 hours after discharge

8. Cost of hospital stay episode measured using hospital records at Discharge

Completion date
30/06/2028

Eligibility

Key inclusion criteria
1. CYP aged 2-18 years (up to and including the day before 19th birthday)
2. Acute severe asthma (ASA) presenting to hospital, defined as respiratory distress and documented wheeze – formal prior diagnosis of asthma not required
3. Required high dose "burst" inhaled bronchodilator therapy – 3 doses of salbutamol ± ipratropium ± nebulised magnesium
4. Failure to respond, defined as persisting hypoxaemia (pulse oxygen saturation less than 95% in air) with moderate or severe respiratory distress, at any point 1 to 4 hours after commencing burst.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
2 Years

Upper age limit
18 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Clinical/radiological evidence of bacterial pneumonia: fever >38.5oC plus focal signs on auscultation or chest X-ray
2. Life-threatening asthma: signs of impending respiratory failure warranting imminent intubation
3. Impaired consciousness (AVPU score P or worse)
4. Contraindications to use of high flow humidified oxygen (HiFlo): air leak (pneumothorax, pneumomediastinum or subcutaneous emphysema), , recent (within 6 weeks) bowel surgery, intractable vomiting
5. Other major respiratory, cardiovascular or neurological condition
6. Previous participation in this study

Date of first enrolment
25/03/2026

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Royal Alexandra Children's Hospital
Eastern Road
Brighton
England
BN2 5BE

Study participating centre
East Kent Hospitals University NHS Foundation Trust
Kent & Canterbury Hospital
Ethelbert Road
Canterbury
England
CT1 3NG

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road
Middlesbrough
England
TS4 3BW

Study participating centre
Royal Hospital for Sick Children (Edinburgh)
9 Sciennes Road
Edinburgh
Lothian

Scotland
EH9 1LF

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

Study participating centre
East Lancashire Hospitals NHS Trust
Royal Blackburn Hospital
Haslingden Road
Blackburn
England
BB2 3HH

Study participating centre
Dartford and Gravesham NHS Trust
Darent Valley Hospital
Darenth Wood Road
Dartford
England
DA2 8DA

Study participating centre
Salisbury NHS Foundation Trust
Salisbury District Hospital
Odstock Road
Salisbury
England
SP2 8BJ

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road

Stoke-on-trent
England
ST4 6QG

Sponsor information

Organisation
University Hospitals Sussex NHS Foundation Trust

ROR
https://ror.org/03wvsyq85

Funder(s)

Funder type

Funder Name
National Institute for Health and Care 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

IPD sharing plan summary
Not expected to be made available