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To assess whether humidified oxygen is more effective than standard oxygen therapy in treating children with acute severe asthma

Submission date 21/11/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 21/11/2013	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/05/2018	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
About one third of children admitted to hospital with asthma need oxygen and there are very good reasons why this oxygen should be warmed and humidified. This is to prevent airways becoming blocked with dried-up mucus and airway secretions. However, despite this, almost all children (and adults) seen in Accident & Emergency departments nationwide are routinely given cold (15°C), dry oxygen straight from the wall at the patients bedside. Following transfer to medical wards, practices vary around the country, but most children continue to receive cold, dry oxygen. Of them, many children with asthma complain of sore, dry noses and throats (and even nosebleeds) when given oxygen in hospital because of its dehydrating effects on the airway.
We want to assess whether giving humidified oxygen (either heated or unheated) from the time of admission to hospital, is more effective than the current standard of cold, dry oxygen therapy.

Who can participate?
Children (2-16 years) with acute severe asthma, admitted in any of the participating hospitals can take part in this study.

What does the study involve?
Patients will be randomly divided to receive one of the following three treatments: standard oxygen therapy, cold humidified oxygen therapy or warm humidified oxygen therapy. Various parameters including side effects and length of the stay in hospital will be assessed.

What are the possible benefits and risks of participating?
There are no benefits or risks associated with taking part in this study and we are not aware of any significant ethical issues raised by being involved in this study.

Where is the study run from?
The study is run from four hospitals in the North-West of England (Alder Hey, Arrowe Park, Warrington, Chester).

When is the study starting and how long is it expected to run for?
The study started in November 2013 and is expected to run until September 2016.

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

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15768

Study information

Scientific Title
A pilot study to assess whether humidified oxygen is more effective than standard oxygen therapy in treating children with acute severe asthma

Acronym
Humox Study

Study objectives

Current study hypothesis as of 15/05/2018:
To determine the most effective treatment for children admitted to hospital with severe asthma, we propose a pilot, randomised controlled trial in which participants will receive either: standard oxygen therapy; warm humidified oxygen; cold humidified oxygen. A range of outcomes will be measured which have previously been assessed as relevant and important by consumers and clinicians. The pilot study will establish which outcome measures can be successfully measured, and provide estimates of effect sizes for these outcomes; a consensus exercise will establish which outcome measure(s) is most relevant and important to consumers and clinicians. This will enable us to plan a larger definitive multicentre study with a definitive primary outcome measure, sample size and robust data to inform recruitment rate in the population and setting under study.

Previous study hypothesis:
To determine the most effective treatment for children admitted to hospital with severe asthma, we propose a pilot, randomised controlled trial in which participants will receive either: standard oxygen therapy; warm humidified oxygen; cold humidified oxygen. A range of outcomes will be measured which have previously been assessed as relevant and important by consumers and clinicians. The pilot study will establish which outcome measures can be successfully measured, and provide estimates of effect sizes for these outcomes; a consensus exercise will establish which outcome measure(s) is most relevant and important to consumers and clinicians. A health economic assessment will investigate the feasibility of collecting the relevant data required to calculate differences in Quality Adjusted Life Years (QALYs) in a definitive study. This will enable us to plan a larger definitive multicentre study with a definitive primary outcome measure, sample size and robust data to inform recruitment rate in the population and setting under study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Liverpool East, 01/11/2013, 13/NW/0738

Study design
Randomised; Interventional; Design type: Treatment

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
Topic: Medicines for Children Research Network; Subtopic: All Diagnoses; Disease: All Diseases

Interventions
The three interventions are:
1. Standard cold, dry (unhumidified) oxygen therapy
2. Cold, humidified oxygen therapy
3. Warm, humidified oxygen therapy

Primary intervention: in the A&E department, each child will be randomised to receive one of the above three treatments.
Heated humidified oxygen will be delivered by a Fisher & Paykel MR850 humidifier and a RT408 OxygenTherapy System through a System facemask (No 1120 or 1100 depending on patient size). The humidifier will be set to a temperature of 31°C and the percentage inspired oxygen titrated to maintain the patients oxygen saturations above 92%. The humidifier will be filled with sterile water.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Length of time continuously spent in oxygen
2. Time until treatment stepped down to hourly, two-hourly and four-hourly nebuliser therapy
3. Differences in oxygen saturation in air at set time points after entry into the study
4. Changes in Yungs Asthma Severity Score and in the Pediatric Respiratory Assessment Measure
5. Number of Salbutamol and Ipratropium Bromide nebules required by each patient following randomisation
6. Requirement for escalation of treatment (i.e. need for intravenous salbutamol/aminophylline or HDU/PICU)
7. Adverse events/tolerability
8. Length of stay in hospital

Secondary outcome measures
Not provided at time of registration

Overall study start date
25/11/2013

Completion date
01/04/2017

Eligibility

Key inclusion criteria
Patients between 2 and 16 years of age attending A&E with a clinical diagnosis of acute severe or potentially life-threatening asthma according to the BTS/SIGN guidelines and who still require oxygen after initial standard nebuliser therapy.

For children 6 years and older, severe asthma will be based on the following criteria being met:
1. Oxygen saturations less than 92% while breathing room air and one of either:
2. Being too breathless to talk in complete sentences
3. Heart rate greater than 120/min
4. Respiratory rate greater than 30/min
5. Use of accessory neck muscles

For children aged 2 to 5 years of age, severe asthma will be based on the following criteria being met:
1. Oxygen saturations less than 92% while breathing room air and one of either:
2. Being too breathless to talk or eat
3. Heart rate greater than 130/min
4. Respiratory rate greater than 50/min
5. Use of accessory neck muscles

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90

Key exclusion criteria
1. Requiring admission to intensive care at time of recruitment
2. Previous participation in this iteration of the Humox study
3. Other significant respiratory disease (chronic lung disease of prematurity, previous significant chest infections)
4. Any other significant underlying medical problem (immunodeficiency, neurological and cardiac conditions)
5. Previously or currently involved with a trial of a medicinal product in the three months preceding screening
6. Parents/guardians who are unable to give informed consent

Date of first enrolment
01/06/2014

Date of final enrolment
01/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Liverpool Children's Hospital NHS Trust
Liverpool
United Kingdom
L12 2AP

Sponsor information

Organisation
Alder Hey Children's Hospital (UK)

Sponsor details
Alder Hey Hospital
Eaton Road West Derby
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04z61sd03

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK)

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
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

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