

Children receiving Heliox Inhalation in Croup: a randomised controlled trial

Submission date 07/10/2006	Recruitment status Stopped	☒ Prospectively registered ☐ Protocol
Registration date 22/02/2007	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 29/11/2012	Condition category Respiratory	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Timothy Coats

Contact details
Emergency Department
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW
tc61@le.ac.uk

Additional identifiers

Study information

Scientific Title

Acronym
CHIC

Study objectives

What effect has Heliox on improving croup score and relieving symptoms in children with croup?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Submitted to the University Hospitals of Leicester (UHL) R&D office and Ethics Committee [UHL 10193]

Primary study design

Interventional

Study design

Randomised double-blind controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Croup (laryngotracheobronchitis)

Interventions

Patients will be randomly allocated to receiving ,additionally to the standard croup treatment, either Heliox21 (study group) or Air (control group). Comparison will be made of the primary and secondary outcome measures, comparing all those allocated to Heliox versus those allocated to Air.

29/11/2012: Please note that this trial was never started due to a lack of funding.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Heliox21

Primary outcome(s)

Modified Westley Croup Score at 30 minutes

Key secondary outcome(s)

1. Croup score at 15 minutes
2. Respiratory rate at 15, 30 minutes
3. Parents assessment of change on Visual Analog Scale
4. Number of epinephrine nebulisers given
5. Requirement for supplemental oxygen therapy
6. Admission to hospital
7. Intubation rate

- 8. Length of stay in ED
- 9. Length of stay in hospital
- 10. Subsequent use of health services

Completion date

01/03/2010

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility

Key inclusion criteria

Children, aged six months to five years, presenting to the Emergency Department (ED) with moderate to severe croup (Modified Westley Croup Score of two or more).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 Months

Upper age limit

5 Years

Sex

Not Specified

Key exclusion criteria

- 1. Children whose oxygen saturation is less than 95%
- 2. Children with known pre-existing lung or airway disease, congenital heart disease, or features suggesting other causes of stridor, such as peritonsillar abscess, epiglottitis or inhaled foreign body

Date of first enrolment

01/03/2007

Date of final enrolment

01/03/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Emergency Department
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

ROR
<https://ror.org/02fha3693>

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration