ISRCTN82240782 https://doi.org/10.1186/ISRCTN82240782

Children receiving Heliox Inhalation in Croup: a randomised controlled trial

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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]

Study design
Randomised double-blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Modified Westley Croup Score at 30 minutes

Secondary outcome measures
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

Overall study start date
01/03/2007

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

Age group
Child

Lower age limit
6 Months

Upper age limit
5 Years

Sex
Not Specified

Target number of participants
142

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
England

United Kingdom

Study participating centre
Emergency Department
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

Sponsor details
Trust Headquarters
Gwendolen House
Gwendolen Road
Leicester
England
United Kingdom
LE5 4QF
djr8@le.ac.uk

Sponsor type
University/education

Website
http://www.uhl-tr.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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