Cuffed versus uncuffed tracheal tubes in small children

Submission date	Recruitment status	Prospectively registered
28/09/2007	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
28/09/2007	Completed	Results
Last Edited	Condition category	Individual participant data
02/02/2015	Surgery	[] Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0436191394

Study information

Scientific Title

Cuffed versus uncuffed tracheal tubes in small children

Study objectives

The main aim of this study is to compare side effects of using a breathing tube with a cuff which is inflated to form a seal around the tube with a tube without a cuff in children from birth to age 5 years undergoing surgery under general anaesthesia. The main measurement used will be the occurrence of noisy breathing (stridor) after the removal of the tube from the airway after surgery is complete.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

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

Surgery: Intubation

Interventions

Cuffed versus uncuffed tracheal tubes

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

Primary aim of the present study is to compare post-extubation airway morbidity as measured as post-extubation stridor after using cuffed tracheal tubes with cuff pressure release valve versus using uncuffed tubes in children from birth up to 5 years.

Secondary outcome measures

Not provided at time of registration

Overall study start date

23/01/2007

Completion date

23/01/2008

Eligibility

Key inclusion criteria

- 1. Children aged from birth (weighing >/= 3kg) to <5 years
- 2. Children requiring oro-tracheal or naso-tracheal intubation as a part of their anaesthetic care and planned ventilatory support during the surgical, interventional or diagnostic procedure.
- 3. Tracheal intubation performed using direct laryngoscopy
- 4. Extubation after the procedure in the operating theatre
- 5. Procedure performed in the supine position
- 6. Patients for elective and emergency surgery and/or interventions if there is no risk of regurgitation or pulmonary aspiration ASA 1 and 2 patients (ie normal or mild systemic disease)
- 7. Written parental consent

Participant type(s)

Patient

Age group

Child

Upper age limit

5 Years

Sex

Both

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

23/01/2007

Date of final enrolment

23/01/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Leeds General Infirmary Leeds United Kingdom LS1 3EX

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

Leeds Teaching Hospitals NHS Trust (UK)

Funder Name

NHS R&D Support Funding

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration