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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

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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
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London
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SW1A 2NL
+44 (0)20 7307 2622
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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 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