

Cuffed versus uncuffed tracheal tubes in small children

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/02/2015	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Surgery: Intubation

Interventions

Cuffed versus uncuffed tracheal tubes

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

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.

Key secondary outcome(s)

Not provided at time of registration

Completion date

23/01/2008

Eligibility**Key inclusion criteria**

1. Children aged from birth (weighing ≥ 3 kg) 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

Healthy volunteers allowed

No

Age group

Child

Upper age limit

5 years

Sex

All

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**

United Kingdom

England

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

Funder(s)

Funder type

Government

Funder Name

Leeds Teaching Hospitals NHS Trust (UK)

Funder Name

NHS R&D Support Funding

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes