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Morbidity associated with perioperative intravenous fluid in children undergoing tonsillectomy

Submission date 12/09/2003	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Stopped	
Last Edited 18/08/2011	**Condition category** Ear, Nose and Throat	

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

N0065091703

Study information

Scientific Title

Study objectives
To see whether giving a bolus of 20 ml intravenous dextrose 4%/saline 0.18% fluid reduces postoperative nausea and vomiting in children undergoing tonsillectomy.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Ear, Nose and Throat: Tonsillectomy

Interventions
Randomised controlled trial, patient, parent and ward nurses blinded to limb allocation, half the study group will receive a measured amount of intravenous fluid during the operation and half will not receive this intravenous fluid.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

The incidence and severity of vomiting, pain and activity disturbance will be monitored and recorded for 3 days post surgery.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2001

Completion date
01/07/2003

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
Children aged between 2 and 15 years, both male and female undergoing tonsillectomy will be recruited.

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
15 Years

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/2001

Date of final enrolment
01/07/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Anaesthesia
Sunderland
United Kingdom
SR4 7TP

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
City Hospitals Sunderland NHS Trust (UK)

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