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Pain relief in children after day-case tonsillectomy.

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/05/2010	Signs and Symptoms	[ ] 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
N0112133830

Study information

Scientific Title

Study objectives
The provision of a painkiller chart to parents of children undergoing tonsillectomy does not reduce pain and improve recovery in children after the procedure.

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

Health condition(s) or problem(s) studied
Signs and Symptoms: Post-operative pain

Interventions
Please note that as of 26/05/10 the status of this trial was changed to "stopped". The trial was discontinued due to lack of funding.

1. Parents of the child booked in for day case tonsillectomy will receive a Patients Information Sheet at their out-patients appointment
2. The anaesthetist concerned will obtain consent for participation in the study from the child's parent on the morning of the surgery
3. The children will be randomised by St Helier on the day surgery unit
4. They will receive a standard anaesthetic and have routine monitoring
5. The children will have routine recovery care
6. They will have standard painkillers to take home with written instructions on bottle
7. Information on discharge: anaesthetist tells parents to give analgesia regularly to their child, even if not in pain. Both groups to receive pain score and recovery indicator questionnaire
8. One group will receive a "painkiller chart" and the control group will not

9. Parents will receive telephone call on day 1, 3 and 7 after tonsillectomy to remind them to fill out questionnaire.
10. Questionnaire will be collected at the two week follow-up clinic by Mr Rathod, Ear, Nose and Throat (ENT) Surgeon

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Pain scores as measured on two separate visual analogue scales
2. Recovery indicators i.e. time to normal diet, time to normal sleeping patterns, nausea and vomiting and need to ring hospital/GP for advice regarding pain control

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2003

Completion date
31/08/2004

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Will be aged 5-10 years
2. Will be undergoing tonsillectomy as a day case procedure at Queen Mary's Hospital Day Theatre
3. Will be healthy children, American Society of Anesthesiologists (ASA) I and II

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Children already on analgesics, children who have a contraindication or allergy to ibuprofen /paracetamol and children who experience unexpected complications perioperatively.

Date of first enrolment
01/09/2003

Date of final enrolment
31/08/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Epsom and St Helier University Hospitals NHS Trust
Carshalton
United Kingdom
SM5 1AA

Sponsor information

Organisation
Department of Health

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

Sponsor type
Government

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Epsom and St Helier University Hospitals 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