

Pain relief in children after day-case tonsillectomy.

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 Years

Upper age limit

10 Years

Sex

All

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

United Kingdom

England

Study participating centre

Epsom and St Helier University Hospitals NHS Trust

Carshalton

United Kingdom

SM5 1AA

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Epsom and St Helier University Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration