

Comparative study of pain levels following paediatric tonsillectomy using either conventional tonsillectomy instruments or the coblator device for tonsil removal

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 24/11/2011	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr D Parker

Contact details

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Additional identifiers

Protocol serial number

N0077117132

Study information

Scientific Title

Study objectives

Coblator tonsillectomy in children produces less post operative pain than the use of conventional surgical techniques.

Randomised entry. Computer generated-opaque envelope same surgeon/anesthetist removal of tonsils either by conventional steel reusable tonsillectomy instruments or disposable coblator wand. Validated pain charts to assess pain scores - Wong and Baker in 24 h post operation as inpatient.

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)

Not Specified

Health condition(s) or problem(s) studied

Signs and Symptoms: Pain

Interventions

Removal of tonsils either by conventional steel reusable tonsillectomy instruments or disposable coblator wand

Intervention Type

Device

Phase

Not Specified

Primary outcome(s)

1. Pain scores days 1, 2, 4, 7 and 10 days
2. Analgesia requirements 1, 2, 4, 7 and 10 days
3. Dietary intake - return to normal diet point

Key secondary outcome(s))

Not provided at time of registration

Completion date

05/08/2004

Eligibility

Key inclusion criteria

Children aged 4-12 undergoing tonsillectomy from Mr Parker's waiting list at the Children's Hospital.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

4 years

Upper age limit

12 years

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/09/2002

Date of final enrolment

05/08/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Southern Derbyshire Acute Hospitals NHS Trust

Derby

United Kingdom

DE1 2QY

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Southern Derbyshire Acute Hospitals NHS Trust (UK)

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?
Results article	results	01/06/2009		Yes	No