

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/2002

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

Age group

Child

Lower age limit

4 Years

Upper age limit

12 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

01/09/2002

Date of final enrolment

05/08/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Southern Derbyshire Acute Hospitals NHS Trust

Derby

United Kingdom

DE1 2QY

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

Southern Derbyshire Acute 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2009		Yes	No