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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 24/11/2011	**Condition category** Signs and Symptoms	

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