

Prospective randomised controlled study comparing guillotine versus cold dissection tonsillectomy in children at Poole Hospital NHS Trust

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/10/2012	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Parmod K Jain

Contact details
Associate ENT Specialist
Poole Hospital NHS Foundation Trust
Longfleet Road
Poole
United Kingdom
BH15 2JB
+44 01202 448290
parmod.jain@poole.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0186191632

Study information

Scientific Title

Study objectives

To demonstrate the perceived advantage of guillotine tonsillectomy versus cold steel dissection tonsillectomy in children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added August 2008: Poole Hospital NHS Foundation Trust local ethics approval LREC no. 06 /Q2201/49, 30/05/2006

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

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Surgery: Tonsillectomy

Interventions

Guillotine versus cold dissection tonsillectomy.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Compare the perceived advantages of guillotine tonsillectomy versus cold steel dissection in children.

Secondary outcome measures

1. Duration of procedure
2. Blood Loss
3. Methods required to arrest bleeding during the operation Pain scores after operation
4. Complication rates after the operation, in particular bleeding rates

Overall study start date

08/03/2007

Completion date

31/03/2010

Eligibility**Key inclusion criteria**

Children aged 3 to 12 undergoing a tonsillectomy.

Participant type(s)

Patient

Age group

Child

Lower age limit

3 Years

Upper age limit

12 Years

Sex

Not Specified

Target number of participants

100

Key exclusion criteria

1. Previous quinsy
2. Bleeding clotting disorder
3. Concurrent adenoidectomy

Date of first enrolment

08/03/2007

Date of final enrolment

31/03/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Associate ENT Specialist

Poole

United Kingdom

BH15 2JB

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Poole Hospital NHS Foundation Trust (UK) NHS R&D Support Funding

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	01/11/2012		Yes	No