

The use of pre-operative analgesia and intra-operative intra-crestal anaesthesia on teeth being extracted or restored under general anaesthetic for post-operative pain control in paediatric dentistry.

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/09/2013	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss Joanna Johnson

Contact details
Paediatric Dentistry
22nd Floor, Guy's Tower
Guy's Hospital
St Thomas' Street
London
United Kingdom
SE1 9RT
+44 (0)20 7881 7881

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0013160113

Study information

Scientific Title

Study objectives

To evaluate the effectiveness of pre-emptive analgesia in children aged 5-12 years undergoing a dental general anaesthetic (DGA) for dental extractions +/- restorations.

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

Oral Health

Interventions

This is a randomised controlled trial utilising the half mouth design whereby patients undergoing extractions +/- restorative care will receive intra-setpal/crestal local anaesthetic in one side of the mouth versus nothing in the control side - each child will act as their own control. Standard post operative analgesia will be administered.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The effectiveness of intra-crestal analgesia for pain control in children.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/06/2004

Completion date

01/06/2006

Eligibility

Key inclusion criteria

Children aged 5-12 years undergoing DGA requiring symmetrical extractions +/- restorations under day stay DGA.

Participant type(s)

Patient

Age group

Child

Lower age limit

5 Years

Upper age limit

12 Years

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

1. Children unsuitable for day case dental general anaesthesia
2. Children aged < 5 years old
3. Children aged > 12 years old
4. Children at risk of endocarditis
5. Children with learning disabilities

Date of first enrolment

01/06/2004

Date of final enrolment

01/06/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Paediatric Dentistry

London

United Kingdom

SE1 9RT

Sponsor information

Organisation

Department of Health

Sponsor details

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

Guy's and St. Thomas' NHS Foundation Trust (UK) Own account 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