

A randomised controlled trial investigating the efficacy and safety of topical anaesthetic (0.25% Bupivacaine [Marcain]) in paediatric patients for the management of distress following dental extractions under general anaesthesia

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 14/01/2009	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0453113836

Study information

Scientific Title

Study objectives

To investigate the effectiveness of topical anaesthetic (0.25% Bupivacaine) for reducing postoperative distress caused by pain in paediatric patients undergoing dental extractions under general anaesthesia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Bupivacaine vs standard practice

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Oral Health: Anaesthesia/Sedation

Interventions

Prospective randomised clinical trial comparing use of topical anaesthetic against no postoperative anaesthetic.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Bupivacaine

Primary outcome(s)

Reduction of distress in children who have had teeth extracted under general anaesthesia.

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/04/2003

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

04/10/2002

Date of final enrolment

30/04/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Central Manchester Healthcare NHS Trust

Manchester

United Kingdom

M15 6FH

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Central Manchester and Manchester Children's University 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	01/11/2004		Yes	No