ISRCTN32315461 https://doi.org/10.1186/ISRCTN32315461

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 14/01/2009	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr IC Mackie

Contact details
Central Manchester Healthcare NHS Trust
Dental Hospital
Higher Cambridge Street
Manchester
United Kingdom
M15 6FH
+44 (0)161 275 6702

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Bupivacaine vs standard practice

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
04/10/2002

Completion date
30/04/2003

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Child

Sex
Not Specified

Target number of participants
Added January 2009: 135

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
England

United Kingdom

Study participating centre
Central Manchester Healthcare NHS Trust
Manchester
United Kingdom
M15 6FH

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