

# 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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	
<b>Last Edited</b> 14/01/2009	<b>Condition category</b> 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?
<a href="#">Results article</a>	results	01/11/2004		Yes	No