

# A RCT investigation: paracetamol and ibuprofen in paediatric patients for management of pain following dental extractions under general anaesthesia

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/02/2010	<b>Condition category</b> Oral Health	<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 I C Mackie

### Contact details

Central Manchester & Manchester Children's Uni Hospitals NHS Trust  
Dental Hospital  
Higher Cambridge Street  
Manchester  
United Kingdom  
M15 6FH  
+44 (0)161 275 6702  
[ian.mackie@manchester.ac.uk](mailto:ian.mackie@manchester.ac.uk)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N0453150124

# Study information

## Scientific Title

### Study objectives

Can post operative distress be reduced by administering a mixture of paracetamol and ibuprofen when compared with paracetamol or ibuprofen alone?

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised double blind controlled clinical study

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

## Participant information sheet

### Health condition(s) or problem(s) studied

Oral Health

### Interventions

Paracetamol and ibuprofen vs paracetamol or ibuprofen alone

### Intervention Type

Drug

### Phase

Not Applicable

### Drug/device/biological/vaccine name(s)

paracetamol and ibuprofen

**Primary outcome measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/07/2004

**Completion date**

01/01/2005

## Eligibility

**Key inclusion criteria**

Not provided at time of registration

**Participant type(s)**

Patient

**Age group**

Child

**Sex**

Not Specified

**Target number of participants**

188 with between 1 and 12 teeth extractions, 47 in each group

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/07/2004

**Date of final enrolment**

01/01/2005

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Central Manchester & Manchester Children's Uni Hospitals NHS Trust  
Manchester

United Kingdom  
M15 6FH

## 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

Central Manchester and Manchester Children's University Hospitals NHS 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?
<a href="#">Results article</a>	results	01/05/2007		Yes	No