ISRCTN12132224 https://doi.org/10.1186/ISRCTN12132224

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

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 08/02/2010	**Condition category** Oral Health	

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
iain.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?
Results article	results	01/05/2007		Yes	No