ISRCTN98093105 https://doi.org/10.1186/ISRCTN98093105

Use of analgesic for children having dental treatment under local anaesthesia

Submission date 08/02/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/05/2009	**Overall study status** Completed	
Last Edited 24/07/2020	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 5

Study information

Scientific Title
Use of preoperative analgesic agents for children having dental treatment under local anaesthesia: a pilot randomised clinical controlled trial

Study objectives
Preoperative ibuprofen will reduce post-operative pain in children having dental treatment under local anaesthetic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
UCLH Research Ethics Committee A - submission pending

Study design
Pilot randomised placebo-controlled double-blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Postoperative pain after dental treatment in children

Interventions
Intervention group will be given ibuprofen syrup (oral):
4-7 years: 150 mg
7-10 years: 200 mg
10-12 years: 300 mg
12-18 years: 300-400 mg

Control group: placebo

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
The post-operative pain intensity score recorded using faces pain scale for the age group between 5-7 years, and the faces pain scale and Visual Analogue Scale (for accuracy) for the age group between 7-18 years. Measured 2, 4 and 6 hours after operation.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/09/2013

Completion date
01/05/2015

Eligibility

Key inclusion criteria
1. Children, both males and females, aged between 5 to 18 years
2. Children undergoing pulp treatment, preformed crowns, extraction, or surgical procedures under local anaesthesia

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Children who have medical condition that excludes them having ibuprofen such as bronchial asthma, allergy to non-steroidal anti-inflammatory drugs, bleeding disorders and renal and hepatic impairment
2. Any child with mental disability that prevent them from completing the pain scoring form

3. Any child who is allergic to paracetamol (as participants will be advised to take this post-operatively if additional painkillers are required postoperatively)
4. Any child who received any analgesic within 8 hours before the treatment
5. Any child who is involved in current research or has recently been involved in any research prior to recruitment

Date of first enrolment
01/09/2013

Date of final enrolment
01/05/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UCL Eastman Dental Institute
London
United Kingdom
WC1X 8LD

Sponsor information

Organisation
University College London Hospital (UK)

Sponsor details
235 Euston Road
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University College London

Alternative Name(s)
University College London in United Kingdom, Collegium Universitatis Londinensis, UCL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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