

Use of analgesic for children having dental treatment under local anaesthesia

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Paul Ashley

Contact details
Alexandra Wing, first floor
UCL Eastman Dental Institute
256 Gray's Inn Road
London
United Kingdom
WC1X 8LD
+44 (0)20 79151269
p.ashley@eastman.ucl.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 years

Upper age limit

18 years

Sex

All

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

United Kingdom

England

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

Sponsor information

Organisation
University College London Hospital (UK)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

