

# Use of analgesic for children having dental treatment under local anaesthesia

<b>Submission date</b> 08/02/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 05/05/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 24/07/2020	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## 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

