

# An investigation into the use of perioperative local analgesia in children undergoing dental treatment under day stay general anaesthesia

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/06/2008	<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 P Ashley

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

## Scientific Title

### Study objectives

Will the different preoperative local analgesia techniques affect the post-operative discomfort, pain and anxiety experienced in children below 6 years old undergoing dental treatment under general anaesthesia?

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Prospective, double blind with a balanced design

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

## Participant information sheet

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

Oral Health: Anaesthesia/Sedation

### Interventions

1. Perioperative local analgesia delivered by infiltration
2. Perioperative local analgesia delivered by intraligamentary injection
3. No perioperative local analgesia

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome measure

Level of pain, anxiety and discomfort.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/03/2002

**Completion date**

01/05/2004

## **Eligibility**

**Key inclusion criteria**

Not provided at time of registration

**Participant type(s)**

Patient

**Age group**

Child

**Sex**

Not Specified

**Target number of participants**

120 patients from Paediatric Dentistry

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/03/2002

**Date of final enrolment**

01/05/2004

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Department of Paediatric Dentistry**  
London  
United Kingdom  
WC1X 8LD

## **Sponsor information**

### **Organisation**

Department of Health (UK)

### **Sponsor details**

Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

### **Sponsor type**

Government

### **Website**

<http://www.doh.gov.uk>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

University College London Hospitals NHS Trust (UK)

## **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 published	22/09/2007		Yes	No