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

Submission date 12/09/2003	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li><li>Protocol</li></ul>
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>
Last Edited 26/06/2008	<b>Condition category</b> Oral Health	[] 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

N0263111537

### 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 intraligamental 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?
<u>Results article</u>	results published	22/09/2007		Yes	No