

# The effect of local anaesthetic on pain following oral surgery under general anaesthetic

<b>Submission date</b> 11/12/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/05/2016	<b>Condition category</b> Surgery	<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

### Contact name

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2008-000254-13

### Protocol serial number

RD/613/07

## Study information

**Scientific Title**

A double blind randomised placebo controlled study assessing the effect of intra-operative local anaesthetic administration on post-operative pain in adolescent children undergoing oral surgery under general anaesthetic to facilitate orthodontic treatment

**Study objectives**

Intra-operative administration of local anaesthetic significantly reduces post-operative pain experience in children aged 12 to 16 years having ambulatory oral surgery to facilitate orthodontic treatment under general anaesthetic.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

South East Wales REC Panel B, 14/10/2008, ref: 08/WSE02/57

**Study design**

Double-blind randomised placebo-controlled study

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Pain following ambulatory oral surgery

**Interventions**

Treatment group: standard dental local anaesthetic in the form 2% lidocaine hydrochloride with 1 in 80000 adrenaline by local injection  
Control group: saline by local injection

Treatment takes place on a single day. No follow-up.

**Intervention Type**

Drug

**Phase**

Not Applicable

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

Lidocaine hydrochloride

**Primary outcome(s)**

Post-surgical pain using a Visual Analogue Scale, measured pre-surgery, at 30 minutes, 1 hour and 2 hours post-surgery.

**Key secondary outcome(s))**

Measurement of time to rescue analgesia.

**Completion date**

20/02/2010

## **Eligibility**

**Key inclusion criteria**

1. Aged 12 to 16 years, either sex
2. Requiring surgery necessitating the raising of a mucoperiosteal flap and bone removal in at least one but not more than two sites
3. Suitable for ambulatory surgery

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

12 years

**Upper age limit**

16 years

**Sex**

All

**Key exclusion criteria**

1. Age under 12 years
2. History of allergy to local anaesthetic of the amide type or to any components of the injectable formulation, paracetamol or non-steroidal anti-inflammatory drugs

Exclusion criteria due to the presence of adrenaline in the local anaesthetic formula:

3. Arterial hypertension
4. Coronary disease
5. Valvular heart disease

Standard anaesthetic-based exclusions for ambulatory surgery:

6. American Society of Anaesthesiologists (ASA) grade greater than 2
7. Body mass index greater than 35
8. Poorly controlled asthma

**Date of first enrolment**

20/02/2009

**Date of final enrolment**

20/02/2010

# Locations

## Countries of recruitment

United Kingdom

Wales

## Study participating centre

Royal Gwent Hospital

Newport

United Kingdom

NP20 2UB

# Sponsor information

## Organisation

Gwent Healthcare NHS Trust (UK)

## ROR

<https://ror.org/045gxp391>

# Funder(s)

## Funder type

Government

## Funder Name

Gwent Healthcare NHS Trust (UK)

# Results and Publications

## 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="#">HRA research summary</a>			28/06/2023	No	No

