

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

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

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Additional identifiers

EudraCT/CTIS number

2008-000254-13

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

Measurement of time to rescue analgesia.

Overall study start date

20/02/2009

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

Age group

Child

Lower age limit

12 Years

Upper age limit

16 Years

Sex

Both

Target number of participants

68

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)

Sponsor details

Research and Development Department

The Friars

Newport

Wales

United Kingdom

NP20 4EZ

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mike.murphy@gwent.wales.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.wales.nhs.uk/sites3/home.cfm?orgid=79>

ROR

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

Funder(s)

Funder type

Government

Funder Name

Gwent Healthcare 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?
HRA research summary			28/06/2023	No	No