

Clinical evaluation of the effects of paediatric dental general anaesthesia and midazolam sedation on cognitive function, anxiety and access to future dental care

Submission date 09/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/01/2010	Condition category Oral Health	<input type="checkbox"/> Individual participant data

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CZH/4/139

Study information

Scientific Title

Study objectives

The study is a prospective, placebo-controlled and randomised trial of midazolam premedication for dental general anaesthesia. It is hypothesised that:

1. Midazolam will interact with general anaesthesia to exacerbate postanaesthetic cognitive impairment
2. Midazolam will reduce pre-operative anxiety and facilitate children's coping with the procedure
3. The reduction in anxiety will be associated with improved future dental attendance patterns

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Placebo controlled randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Dental caries requiring multiple extractions

Interventions

1. General anaesthesia due to child's inability to cope whilst conscious
2. Midazolam versus placebo to reduce pre-operative anxiety

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Midazolam

Primary outcome measure

1. Cognitive function postoperatively
2. Anxiety pre-operatively
3. Interaction between general anaesthesia and midazolam

Secondary outcome measures

Future dental attendance patterns.

Overall study start date

01/01/2004

Completion date

31/05/2006

Eligibility

Key inclusion criteria

Children aged 5-10 years having multiple dental extractions under general anaesthesia due to their inability to cope with conscious sedation.

Participant type(s)

Patient

Age group

Child

Lower age limit

5 Years

Upper age limit

10 Years

Sex

Both

Target number of participants

200

Key exclusion criteria

1. English not first language
2. Learning disability
3. Neurological disorder
4. Psychiatric disorder
5. Respiratory disorder

Date of first enrolment

01/01/2004

Date of final enrolment

31/05/2006

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre**Psychological Medicine**

Glasgow

United Kingdom

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Sponsor information

Organisation

Scottish Executive Chief Scientist Office (UK)

Sponsor details

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Sponsor type

Government

Website

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

ROR

<https://ror.org/01613vh25>

Funder(s)

Funder type

Government

Funder Name

Scottish Executive Chief Scientist Office (ref: CZH/4/139) (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?
Results article	results of effects on postoperative cognition	01/09/2007		Yes	No
Results article	results of effects on dental anxiety, anaesthetic induction and psychological morbidity	11/07/2009		Yes	No