

A comparison of patient-controlled sedation and operator-controlled intravenous sedation with midazolam in patients undergoing surgical removal of impacted third molars

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/01/2020	Condition category Oral Health	<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

Dr Ana-Maria Roman

Contact details

Holtye Road
West Sussex
East Grinstead
United Kingdom
RH19 3DZ
+44 (0)1342 414000
hf@cct.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0190137104

Study information

Scientific Title

-

Study objectives

To assess the safety and effectiveness of patient-controlled sedation with midazolam compared with the currently used technique of operator-controlled sedation with midazolam in healthy patients undergoing surgical removal of lower third molars.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

A randomised cross-over prospective trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Surgical removal of impacted third molars

Interventions

N = 64 (+ 20% to allow for drop-outs) p = 0.05; power 0.8; effect size 0.3; tests: repeated measures t-test (normal distribution) or Wilcoxon signed ranks test (non-parametric).

Patients are randomised to:

1. Patient-controlled sedation with midazolam
2. Operator-controlled sedation with midazolam

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Midazolam

Primary outcome measure

1. Demographic, medical and dental status
2. Duration of sedation induction and operation
3. Level of sedation (score at 10, 20, 30 minutes following the end of the procedure)
4. Operating conditions
5. Vital signs
6. Anxiety assessment (by asking the patients to indicate their level of anxiety on a visual analogue scale [VAS] - 100 mm)
7. Memory and acceptability - once recovered, patients are asked whether they can remember specific events during the appointment. Following the second appointment, patients are asked to specify which session provided the most acceptable level of sedation and anxiolysis.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2004

Completion date

30/10/2004

Eligibility

Key inclusion criteria

1. American Society of Anaesthesiologists (ASA) grade I - II
2. Require surgical removal of bilateral similarly impacted lower third molars (equal surgical difficulty) at two visits
3. Can bring a responsible person to accompany them home

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

N = 64

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/04/2004

Date of final enrolment

30/10/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Holtye Road

East Grinstead

United Kingdom

RH19 3DZ

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Queen Victoria Hospital 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