ISRCTN43878832 https://doi.org/10.1186/ISRCTN43878832

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

Registration date
30/09/2004

Overall study status
Completed

Last Edited
03/01/2020

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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