

Fixed-time chlorazepate dipotassium premedication versus midazolam on demand: a randomised, controlled trial

Submission date 13/12/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 13/02/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/03/2021	Condition category Surgery	☐ 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

Study information

Scientific Title
Fixed-time chlorazepate dipotassium premedication versus midazolam on demand: a randomised, controlled trial

Acronym

premedication

Study objectives

We hypothesised that:

1. 50 mg clorazepate dipotassium at 10 pm evening before surgery prevent an increase of anxiety and sympatho-adrenal activity at morning of surgery sufficiently, and
2. A fixed-time application of clorazepate dipotassium at 7 am morning of surgery may be superior compared to administration of midazolam 30 minutes prior to induction of anesthesia with respect to level of anxiety, sympatho-adrenal activity and conscious sedation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The trial was approved by the local ethics committee of the University Kiel on the 3rd April 2002 (reference number: AZ 142/01).

Primary study design

Interventional

Study design

Randomised double-blind placebo-controlled study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Premedication, Anaesthesia

Interventions

Patients were randomised to one of two groups:

1. Group CCP: at Evening Before Surgery (EBS) clorazepate dipotassium 50 mg orally (Tranxilium®; Sanofi-Aventis GmbH, Frankfurt am Main, Germany); at Morning Of Surgery (MOS) clorazepate dipotassium 25 mg orally; and before Induction of Anesthesia (AI) placebo orally
2. Group CPM: at EBS clorazepate dipotassium 50 mg orally; at MOS placebo orally; before AI midazolam 7.5 mg orally (Dormicum®; Roche, Mijdrecht, The Netherlands)

Dosages of clorazepate dipotassium in our study were based on recommendations that have been published previously.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Chlorazepate dipotassium and midazolam

Primary outcome(s)

1. Level of anxiety
2. Sympatho-adrenal activity (plasma levels of Adrenocorticotrophic Hormone [ACTH], cortisol, norepinephrine and epinephrine)

Key secondary outcome(s)

1. Haemodynamic data
2. Oxygen saturation
3. Conscious sedation
4. Bispectral index

Completion date

01/10/2004

Eligibility

Key inclusion criteria

1. Patients with an American Society of Anaesthesiologists (ASA) physical status of one or two
2. Aged between 18 and 55 years
3. Weighing from 60 to 88 kg
4. Scheduled to undergo an elective surgical, orthopaedic or urologic procedure in general anesthesia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Total final enrolment

50

Key exclusion criteria

1. Sleep apnoea syndrome
2. Pregnancy
3. Use of sedative, stimulant, or other medications within the previous month
4. The presence of neurological, renal, or hepatic disease

Date of first enrolment

01/05/2003

Date of final enrolment

01/10/2004

Locations

Countries of recruitment

Germany

Study participating centre

University Hospital Schleswig-Holstein

Kiel

Germany

24105

Sponsor information

Organisation

University Hospital Schleswig-Holstein (Germany)

ROR

<https://ror.org/01tvm6f46>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital Schleswig-Holstein (Germany)

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?
Results article		01/09/2007	26/03/2021	Yes	No

