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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/02/2007	**Overall study status** Completed	
Last Edited 26/03/2021	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Patrick Meybohm

Contact details
University Hospital Schleswig-Holstein
Campus Kiel
Schwanenweg 21
Kiel
Germany
24105
-
meybohm@anaesthesie.uni-kiel.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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 chlorazepate 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 chlorazepate 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).

Study design
Randomised double-blind placebo-controlled study

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

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

Overall study start date
01/05/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
50

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)

Sponsor details
Campus Kiel
Department of Anaesthesiology and Intensive Care Medicine
Schwanenweg 21
Kiel
Germany
24105

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01tvm6f46

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Schleswig-Holstein (Germany)

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		01/09/2007	26/03/2021	Yes	No