

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

<b>Submission date</b> 13/12/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 13/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/03/2021	<b>Condition category</b> Surgery	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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**

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 Adrenocorticotrophic 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?
<a href="#">Results article</a>		01/09/2007	26/03/2021	Yes	No