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# An investigative study into the recovery index, attentiveness and state of memory after xenon or isoflurane anaesthesia

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| **Submission date**<br>30/12/2009 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>16/03/2010 | **Overall study status**<br>Completed | |
| **Last Edited**<br>25/05/2010 | **Condition category**<br>Surgery | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Ralph Stuttmann

**Contact details**
Mersburgerstraße 165
Halle ( Saale)
Germany
06112
ralph.stuttmann@bergmannstrost.com

## Additional identifiers

**Protocol serial number**
23/2002

## Study information

**Scientific Title**
A single centre randomised controlled investigative study into the recovery index, attentiveness and state of memory after xenon or isoflurane anaesthesia

## Study objectives
The aim of the study was to evaluate the efficacy of two balanced anaesthetic regimens with respect to recovery of early post-operative cognitive function at the day of operation (assessed as attentiveness and memory; this was the primary criterion) and emergence profile (assessed as the recovery index; this was the secondary criterion). The hypothesis was primarily that patients have a significantly higher status of attentiveness and memory 1 and 3 hours after inhalation anaesthesia with xenon compared to isoflurane anaesthesia, and that patients reach their pre-operative level of cognitive function within 3 hours after extubation. The second hypotheses was that the time to wake up from the anaesthetic was predicted to be shorter following xenon than following isoflurane.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics Committee of the University Witten/Herdecke approved on the 11th September 2002 (ref: 23/2002). Patient insurance by Winterthur International (ref: DE 00020283-LI-02A-715).

## Study design
Single centre single blind randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Post-operative cognitive function

## Interventions
ASA I and II patients undergoing both long and short surgical interventions were randomised to receive either general anaesthesia with xenon or general anaesthesia with isoflurane. The inhalational anaesthesia was carried out following standard procedures using appropriate equipment.

Patients were randomised in blocks of 4 - 8 patients in order to balance the groups. The varying size of blocks was to counteract the differing frequencies of the operations and also any influence of duration and invasiveness of the operations. A total of 61 patients who met the pre-defined inclusion and exclusion criteria were randomised either to receive xenon in oxygen (Xenon group, n = 31) or isoflurane in stickoxydal (Isoflurane group, n = 30).

## Intervention Type
Drug

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Xenon, isoflurane

### Primary outcome(s)
Syndrome Short Test

### Key secondary outcome(s))
1. Recovery Index
2. Aldrete Score

### Completion date
31/05/2005

## Eligibility

### Key inclusion criteria
1. Healthy American Society of Anaesthesiologists (ASA) grade I and II patients
2. Aged over 18 years of age, either sex
3. Scheduled for four different types of elective surgery. The types of surgery were:
3.1. Visceral surgical strumectomy
3.2. Augmentation or reduction mammaplasty
3.3. Liposuction in obese patients
3.4. Knee arthroscopy

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Patients with ASA classification grade greater than 2
2. Aged less than 18 years
3. Emergency surgery
4. Alcohol or drug abuse
5. Organ dysfunction of liver, kidney or pulmonary system
6. Diabetes

### Date of first enrolment
01/06/2003

### Date of final enrolment
31/05/2005

# Locations

### Countries of recruitment
Germany

### Study participating centre
**Mersburgerstraße 165**
Halle ( Saale)
Germany
06112

# Sponsor information

### Organisation
BG-Kliniken Bergmannstrost (Germany)

### ROR
https://ror.org/042g9vq32

# Funder(s)

### Funder type
Industry

### Funder Name
Messer Griesheim/AIR LIQUIDE Medical GmbH (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 | results | 07/05/2010 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |