

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

Submission date 30/12/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 16/03/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/05/2010	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

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).

Primary study design

Interventional

Study design

Single centre single blind randomised controlled trial

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 mammoplasty
 - 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