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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/03/2010	**Overall study status** Completed	
Last Edited 25/05/2010	**Condition category** 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Syndrome Short Test

Secondary outcome measures
1. Recovery Index
2. Aldrete Score

Overall study start date
01/06/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
61

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)

Sponsor details
c/o PD Dr. med. Ralph Stuttmann
Merseburgerstraße 165
Halle

Germany
06112
ralph.stuttmann@bergmannstrost.com

Sponsor type
Hospital/treatment centre

Website
http://www.bergmannstrost.com

ROR
https://ror.org/042g9vq32

Funder(s)

Funder type
Industry

Funder Name
Messer Griesheim/AIR LIQUIDE Medical GmbH (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	results	07/05/2010		Yes	No