

Does Bispectral index monitoring during anesthesia provide benefit for elderly patients?

Submission date 23/02/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/03/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/03/2015	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Bispectral index (BIS) is a method used to monitor the depth of anesthesia. Administration of anesthetics in response to individual need as estimated BIS has been associated with reduced risk of awareness, reduced consumption of anesthetics, faster emergence from anesthesia and reduced incidence of postoperative nausea and vomiting. Although controversial, an impact on long-term mortality has been proposed. There are neuro-monitoring devices available but they are not used routinely, which shows that it is still not clear whether these technologies actually provide sufficient benefit to be cost effective. This aim of this study is to provide a carefully controlled global view on BIS monitoring during anesthesia that will be relevant to patients, anesthesia providers and the community.

Who can participate?

Patients 70 years or older undergoing major, elective, non-cardiac surgery.

What does the study involve?

BIS is recorded for all participants.

Then participants are randomly allocated to one of two groups: "open group" or "concealed group",

BIS is available for guiding administration of anesthetics for participants in the "open group". BIS data is recorded for subsequent analysis for participants in the "concealed" group.

A third group of age and gender matched people not undergoing surgery is recruited in order to correct cognitive testing results in the two study groups (for random variation over time and learning effect).

What are the possible benefits and risks of participating?

Participants allocated to the "open group" may benefit from more individualized administration of anaesthetics. Participants allocated to the "concealed" group will receive standard care.

Application of BIS electrodes is not associated with any risk. Risks with BIS monitoring have not been demonstrated.

Where is the study run from?

Länssjukhuset, Kalmar (Sweden)

When is the study starting and how long is it expected to run for?
From February 2004 to October 2010

Who is funding the study?
Medical Research Council of South East Sweden

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
Dr Rolf Sandin

Contact details
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A prospective, randomized evaluation of utility of Bispectral index monitoring in elderly surgical patients

Study objectives
The hypothesis is that mean BIS values would be closer to a predefined target of 50 and significantly different from when no data from BIS monitoring is available, and that this anticipated difference in BIS between groups should be significantly related to improved outcome. Twenty-five outcome variables were allocated to one of three meaningful domains which constitute primary outcome. These domains are postoperative cognitive decline, perioperative cardiovascular compromise, and a socio-economic oriented domain. We anticipate that potential benefits from individualized BIS guided anesthesia would be most obvious in the elderly population undergoing long procedures. Therefore we conduct this investigation in patients 70 years or older undergoing major, elective, non-cardiac surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Regionala Etikprövningsnämnden i Linköping (IRB at Linköping University, Linköping, Sweden), 27/04/2005, reference number M25-5.

Study design

Single-center randomized controlled study

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Improved outcome after anesthesia by more precise administration of anesthetics in relation to individual need as assessed by bispectral index monitoring.

Interventions

In study groups Bispectral index is recorded in all subjects but only available for guiding administration of anesthetics in the "open" group as opposed to the "concealed" group in which data is recorded for subsequent analysis.

Additional control patients not undergoing surgery were recruited to establish the learning effect and natural variation in performance over time in the cognitive testing for postoperative cognitive dysfunction.

Intervention Type

Device

Primary outcome(s)

Postoperative cognitive dysfunction day 7 after surgery, global cardio-vascular outcome score (based on 10 subparameters), and global socio-economic outcome score (based on 8 subparameters)

Key secondary outcome(s)

Intraoperative blood loss, net fluid and blood balance, urine production first 6 h postoperatively, postoperative hypoxemia (defined as SpO₂ below 90%), increase in C-reactive protein postoperative day 3, weight gain postoperative day 3, awareness, 7 subparameters reflecting postoperative cognitive decline as described by Moller et al. (Lancet 1998; 351: 857-61), increase in Troponin-I 12-24 h after surgery, increase in Troponin-I 72 h after surgery, average intraoperative mean arterial blood pressure, duration of heart rate deviating >20% from baseline intraoperatively, duration of heart rate deviating >20% from baseline postoperatively, duration of systolic arterial blood pressure deviating >20% from baseline intraoperatively, duration of systolic arterial blood pressure deviating >20% from baseline postoperatively, duration of intraoperative inotropic support, number of patients given inotropic support postoperatively, duration of inotropic support postoperatively, age corrected average MAC-fraction of sevoflurane administered during anesthesia, duration of stay at the postoperative care unit, number of patients admitted to the ICU postoperatively, duration of total stay at the postoperative care unit and intensive care unit, length of hospital stay, number of patients being discharged to home, 30-day survival, 1-year survival.

Completion date

21/10/2010

Eligibility

Key inclusion criteria

1. Aged over 70, both gender
2. Anticipated duration of surgery over 90 minutes
3. Being able to communicate in Swedish
4. No overt hearing or reading difficulties

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Unstable medical condition starting after inclusion but prior to surgery
2. Psychiatric disease
3. Reoperation
4. Lost to follow-up
5. Result from mini mental state examination <23

Date of first enrolment

01/04/2006

Date of final enrolment

30/10/2009

Locations

Countries of recruitment

Sweden

Study participating centre

Länssjukhuset

Kalmar

Sweden

S-39185

Sponsor information

Organisation

Medical Research Council of South East Sweden - Forskningsrådet i Sydöstra Sverige (FORSS)

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council of South East Sweden - Forskningsrådet i Sydöstra Sverige (FORSS)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes