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

Submission date
23/02/2015

Recruitment status
No longer recruiting

Registration date
17/03/2015

Overall study status
Completed

Last Edited
16/03/2015

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 anaesthesics. 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
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 measure
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)

Secondary outcome measures

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 påatioents admitted to the ICU postoperatively, duration of sotal 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.

Overall study start date
20/02/2004

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

Age group
Adult

Sex
Both

Target number of participants
50 patients in each of the two study groups and 25 age matched control patients not undergoing surgery (control for cognitive testing).

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)

Sponsor details
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Sponsor type
Research council

Website
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Funder(s)

Funder type
Research council

Funder Name

Results and Publications

Publication and dissemination plan
The results are intended to be published in a major scientific journal in the field of anesthesiology.

Intention to publish date
31/05/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request