The BALANCED Anaesthesia Study: A prospective, randomised clinical trial of two levels of anaesthetic depth on patient outcome after major surgery

Published: 05-04-2016
Last updated: 14-04-2024

We are performing a large randomised trial of *deep* versus *light* anaesthesia to definitively answer the question of whether anaesthetic depth alters perioperative outcome. Elderly patients undergoing major surgery will be randomised to an…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Therapeutic procedures and supportive care NEC
Study type	Observational non invasive

Summary

ID

NL-OMON43559

Source
ToetsingOnline

Brief title
The BALANCED study

Condition

- Therapeutic procedures and supportive care NEC

Synonym
Complications of anaesthesia; perioperative complications

Research involving
Human

Sponsors and support

Primary sponsor: Monash University

Source(s) of monetary or material Support: betaling per patient door onderzoekers

Intervention

Keyword: Anaesthesia, Anaesthetic depth, Mortality

Outcome measures

Primary outcome

Primary hypothesis

Light general anaesthesia (BIS = 50) is associated with decreased all cause mortality compared with deep general anaesthesia (BIS = 35) one year after major surgery in elderly patients.

Secondary outcome

Secondary hypotheses

Light general anaesthesia (BIS = 50) is associated with decreased incidences of MI, cardiac arrest, PE, stroke, sepsis and surgical site infection compared with deep general anaesthesia (BIS = 35) at 30 days and one year after major surgery in elderly patients.

Light general anaesthesia (BIS = 50) is associated with decreased incidences of a composite endpoint of MI, cardiac arrest, PE and stroke compared with deep general anaesthesia (BIS = 35) at 30 days and one year after major surgery in elderly patients.

Light general anaesthesia (BIS = 50) is associated with decreased cancer recurrence compared with deep general anaesthesia (BIS = 35) one year after

major surgery in elderly patients.

Light general anaesthesia (BIS=50) is associated with an increased incidence of persistent postoperative pain compared with deep anaesthesia (BIS=35) at 30 days and one year after surgery in elderly patients.

Light anaesthesia (BIS = 50) is associated with increased disability-free survival compared with deep general anaesthesia (BIS = 35) one year after major surgery in elderly patients.

Safety and quality hypotheses

Light general anaesthesia (BIS = 50) is associated with improved early quality of recovery compared with deep general anaesthesia (BIS = 35) after major surgery in elderly patients.

Light general anaesthesia (BIS = 50) does not increase the incidence of awareness compared with deep general anaesthesia (BIS = 35) after major surgery in elderly patients.

Study description

Background summary

Monitors that use the electroencephalogram (EEG) to assess anesthetic depth in patients undergoing surgery are now widely available. General anesthesia that

is performed without depth of anesthesia monitoring, tends to be relatively deep to ensure a lack of awareness. Five of six recent observational studies have shown that deep anesthesia may be associated with an increase in mortality (up to 20%) in moderate or high risk patients undergoing major surgery who receive relatively deep anesthesia, although it is difficult to exclude the effects of other factors such as blood pressure. This also needs to be balanced against a possible increase in the risk of awareness if patients are given lower doses of anesthetic drugs. It is largely unknown how anesthetic depth influences these and other perioperative outcomes.

Study objective

We are performing a large randomised trial of *deep* versus *light* anaesthesia to definitively answer the question of whether anaesthetic depth alters perioperative outcome. Elderly patients undergoing major surgery will be randomised to an anaesthetic targeting either BIS=35 or BIS=50 for the deep and light groups respectively. The primary outcome variable will be all-cause mortality at one year and secondary outcomes will be MI, cardiac arrest, PE, stroke, sepsis, surgical site infection, ICU stay, hospital stay, awareness, WHODAS score, persistent postoperative pain and cancer recurrence.

Study design

International multicentre, prospective, randomised, double blind (subjects, investigators and outcomes assessors), active control, parallel assessment, intention to treat, safety and efficacy study.

Study burden and risks

The burden for patients who participate in this study is limited to completing several short questionnaires during the follow-up period of the study. There are no known additional risks from participating in this study beyond those of general anaesthesia. Currently there are no guidelines on the appropriate depth of anaesthesia to choose during operations. The two depths chosen in this study are within the common range used for general anaesthesia. They are both deeper than the level associated with awareness under anaesthesia. An individualised mean arterial blood pressure target range appropriate for the patient being studied will be set by the anaesthetist before randomisation, which is according to routine care practice.

There are no expected individual benefits for the study participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

*60 years
ASA physical status 3 or 4
Surgery lasting *2 hours
Post-op hospital stay *2 nights
General anaesthesia with or without major regional block
Able to monitor BIS

Exclusion criteria

Unable to monitor BIS (e.g. cranial or intracranial surgery)
Unable to consent

Surgery with *wake-up* test
Propofol infusion for part or all of maintenance of anaesthesia (*total intravenous anaesthesia*), Previous enrolment in Balanced study

Study design

Design

Study type: Observational non invasive

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-08-2016
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	05-04-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	15-02-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	ACTRN12612000632897
CCMO	NL51677.041.15