

# 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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Therapeutic procedures and supportive care NEC
<b>Study type</b>	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

### Public

Monash University

Wellington Road 2  
Clayton, VIC 3800  
AU

### Scientific

Monash University

Wellington Road 2  
Clayton, VIC 3800  
AU

## 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