Routine postsurgical anesthesia visit to improve patient outcome

Published: 29-06-2016
Last updated: 20-04-2024

Does the introduction of routine postsurgical anesthesia visits reduce postoperative 30-day mortality?

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

Summary

ID

NL-OMON46201

Source
ToetsingOnline

Brief title
TRACE study

Condition

- Therapeutic procedures and supportive care NEC

Synonym
Postoperative complications, surgical outcome

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw,Zorgverzekeraars Nederland

Intervention

Keyword: Anesthesia, Complications, Mortality, Postoperative visits, Surgery

Outcome measures

Primary outcome

30-day postoperative mortality, including cost effectiveness research.

Secondary outcome

n.v.t.

Study description

Background summary

In the Netherlands, about 1.4 million undergo anesthesia and surgery on a yearly base. The number of patients in a medium to high-risk population who develop a complication after surgery is estimated at 30%. Postsurgical mortality is mainly caused by the lack of a standardized follow-up of patients who develop a postoperative complication, which results in failure to rescue. The TRACE study aims to investigate whether standardized anesthesia visits on day 1 and 3 following surgery reduces 30-day mortality by decreasing failure to rescue rates.

Study objective

Does the introduction of routine postsurgical anesthesia visits reduce postoperative 30-day mortality?

Study design

A nationwide, multicenter stepped-wedge design study in academic and peripheral hospitals.

Intervention

Interventions: Postoperative visit by an anesthesia professional on day 1 and 3 following the surgical procedure. The postoperative visit will be standardized based on the Modified Early Warning Score (MEWS) that estimates vital function. Standard intervention to be compared to: No postoperative follow-up of patients by an anesthesia professional.

Study burden and risks

Control group: Usual clinical care with 30-day and 12-month follow-up of complications.
Intervention group: Standardized postoperative visit by an anesthesia professional at day 1 and 3 following surgery, MEWS questionnaire, and 30-day and 12-months follow-up of complications.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Adult patients undergoing elective surgery with an indication for postoperative hospital stay
* Meets at least one of the following BonnScore criteria:
o Postoperative pain therapy with follow up by an Acute Pain Service (APS)
o Patients older than 60 years
o Patients older than 45 years and a rCRI greater than 2

o Patients with a sAPGAR smaller than 5
rCRI: The revised Cardiac Risk Index (rCRI) is a clinical prediction tool to estimate the risk of a patient for perioperative cardiac complications. The risk is determined based on the presence of ischemic heart disease, congestive heart failure, cerebrovascular disease (stroke or transient ischemic attack), diabetes requiring preoperative insulin use, chronic kidney disease (creatinine > 2 mg/dL), and/or undergoing suprainguinal vascular, intraperitoneal, or intrathoracic surgery. The risk for cardiac death, nonfatal myocardial infarction, and nonfatal cardiac arrest is 0.4% in case of 0 predictors, 0.9% in case of 1 predictor, 6.6% in case of 2 predictors and 11% in case of 3 or more predictors.
Surgical APGAR score: The surgical APGAR score is used to predict perioperative and postoperative morbidity and mortality based on predicted perioperative blood loss, intraoperative blood pressure and intraoperative heart rate. The score is calculated at the end of a surgical procedure.

Exclusion criteria

* Cardiac surgery
* Preoperative indication for medium care or intensive care admission
* No informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-10-2016
Enrollment:	5600
Type:	Actual

Ethics review

Approved WMO Date:	29-06-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-08-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL56004.029.16