Routine postoperative follow-up for the early diagnosis and treatment of complications

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25503

Source
Nationaal Trial Register

Brief title
TRACE study

Health condition

Anesthesia
Surgery
Complications
MEWS
Failure to rescue

Sponsors and support

Primary sponsor: MUMC+ / VUmc / AMC
Source(s) of monetary or material Support: ZonMw
Zorgverzekeraars Nederland

Intervention

Outcome measures

Primary outcome

30-day mortality

Secondary outcome

- Quality of recovery 30 days after surgery, incidence of myocardial infarction and heart failure, cardiac arrhythmias, kidney failure, pneumonia, embolic complications (pulmonary and stroke), surgical site infection and sepsis.

- Length of stay in hospital, length of stay high care unit (ICU, MCU)

- Postoperative health-related quality of life up to 1 year following surgery using the EQ-5D questionnaire

- Time to implement rescue therapy usually requiring admission at medium care or intensive care unit

- Hospital costs up to 12 months following surgery.

- Cost-effectiveness with 30-days and 12-month time horizon

Study description

Background summary

Rationale: 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.

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.

Study population: Adult patients undergoing elective surgery (n=5600) with an indication for postoperative hospital stay, and who meet at least one of the Bonn score criteria upon admission to the post -anesthesia care unit (PACU): Postoperative pain therapy with follow-up, patients older than 60 years, patients older than 45 years with a revised cardiac risk index greater than 2 or patients with surgical Apgar score of less than 5.

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.

Main study endpoint: 30-day postoperative mortality, including cost effectiveness research.

Study objective

The central hypothesis of our study is that routine postsurgical anesthesia visits reduces postoperative 30-day mortality by 30%.

Study design

30-day outcome

Intervention

Control cohort

In the control cohort, nurses and ward doctors will routinely monitor patients in the postoperative period. A research assistant will register the study endpoints on a case record form.

Intervention cohort

In addition to the routine monitoring of patients by nurses and ward doctors, an

anesthesiologist/resident anesthesiology/physician assistant will visit patients on the first and third day following surgery. This postoperative visit is standardized based on the Modified Early Warning Score (MEWS). The MEWS includes the following measurements:

- Respiratory rate. The respiratory rate will be assessed using visual monitoring.

- Heart rate and rhythm. Heart rate and rhythm will be assessed by palpation of the A. radialis and auscultation.

- Systemic oxygen saturation. Systemic oxygen saturation will be measured by pulse oxymetry during the postoperative visit. In case of a SpO2 below 95%, continuous pulse oxymetry monitoring will be instituted.

- Systolic blood pressure. Systolic blood pressure will be assessed using a manual or electronic blood pressure measurement device.

- Body temperature. Body temperature will be measured using an ear thermometer.

- Level of consciousness. The response to verbal appeal or a pain stimulus will be monitored.

- Urine output. Urine output will be monitored in the patient status.

Other measurements include:

- Visual Analogue Score to assess pain during rest and movement

- Nausea/Vomiting (yes/no)

- Defecation (yes/no)

- Mobilization (none/movements in bed/sitting/ standing/walking)

Contacts

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Eligibility criteria

Inclusion criteria

- 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

o Patients older than 60 years

o Patients older than 45 years and a rCRI greater than 2

o Patients with sAPGAR smaller than 5

rCRI: The 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.

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. The lower the score, the higher the risk for postoperative complications.

Exclusion criteria

- Cardiac surgery

- Preoperative indication for medium care or ICU admission

- No informed consent

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2016
Enrollment:	5600
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL5249
NTR-old	NTR5506
Other	: 80-83700-98-16502

Study results