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

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25503

Bron
Nationaal Trial Register

Verkorte titel
TRACE study

Aandoening

Anesthesia
Surgery
Complications
MEWS
Failure to rescue

Ondersteuning

Primaire sponsor: MUMC+ / VUmc / AMC
Overige ondersteuning: ZonMw
Zorgverzekeraars Nederland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

30-day mortality

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

30-day outcome

Onderzoeksproduct en/of interventie

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)

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Cardiac surgery

- Preoperative indication for medium care or ICU admission

- No informed consent

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2016
Aantal proefpersonen:	5600
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5249
NTR-old	NTR5506

Register	ID
Ander register	: 80-83700-98-16502

Resultaten