Optimal Track: perioperative management of high-risk surgical patients

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To investigate the feasibility of the introduction of a specialized clinical pathway (Optimal Track) for the high risk surgical patient. In this pathway high risk surgical patients will receive treatment according to fast-track principles....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39849

Source ToetsingOnline

Brief title perioperative management of high risk surgical patients

Condition

- Other condition
- Therapeutic procedures and supportive care NEC

Synonym

patients undergoing surgery that have an increased risk on developing complications

Health condition

hoog risico chirurgische patiënten

Research involving

Human

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Sponsors and support

Primary sponsor: De Heel - Zaans Medisch Centrum Source(s) of monetary or material Support: Zorgverzekeraar

Intervention

Keyword: fast-track surgery, hemodynamic monitoring, high risk surgery, perioperative management

Outcome measures

Primary outcome

- 1. Percentage of patients requiring hemodynamic optimization
- 2. Time to hemodynamic optimization
- 3. Investment costs (calculated from a health care perspective, using a

bottom-up approach)

- 4. Accumulated costs during admission
- 5. Total length of hospital stay
- 6. OPT length of stay
- 7. Post-operative mortality (mortality within 30 days after surgery)
- 8. In-hospital morbidity. Diagnosis of complications will be undertaken by

non-research staff. Complications will be verified by a member of the research

staff using specific pre-determined criteria.

9. Quality of life measured with validated questionnaires (SF-36) before, 2

days after and three months after surgery

Secondary outcome

Complications due to arterialline placement

Study description

Background summary

Unfortunately, procedure related morbidity and mortality are an inevitable part of surgical practice. Much research has been directed on strategies that reduce complications due to surgical procedures. Especially the technical aspects of operations and the individual performance of surgeons have been studied intensively. Compared to these aspects the system has been poorly studied although structural changes in perioperative management have been shown to have significant impact on morbidity and mortality. For example, fast track surgery and perioperative hemodynamic optimization have shown to reduce both morbidity and mortality.

Major postoperative complications occur in a relative small group of high risk patients. Various scoring systems have been designed to identify the individual patient at increased risk for developing perioperative mortality and morbidity[8-10]. Identifying these patients has both logistic and clinical advantages. Patients at increased risk may benefit from additional perioperative therapy. Several tools and perioperative management strategies have been proposed and investigated in these high risk surgical patients.

There are many different audit tools designed to estimate the risk of a patient on morbidity and mortality. Their merit in surgical practice has been well established. For this study, the identification of risk in surgical patients score (IRIS) will be used for identifying high-risk patients. This scoring system is a strong predictor of mortality and morbidity in surgical patients treated at the Zaandam Medical Centre (ZMC). Furthermore, it is easy to use and relies on objective parameters. Patients with an IRIS score of four and higher are considered to be at high risk for developing complications.

At this moment high risk surgical patients receive a non-standardized level of care. More intense monitoring of these patients and perioperative hemodynamic optimization has been shown to improve outcome in high risk surgical patients. Furthermore, using fast track principles speeds up the rehabilitation process and diminishes complications that occur due to overlong hospital stay, such as nosocomial infections and pressure ulcers.

In 1988 Shoemaker and colleagues published the results of an observational study on hemodynamic values in surgery, trauma and critically ill patients. Compared to non-surviving patients, survivors demonstrated significantly higher values of oxygen delivery (over 600 ml/min/m2) and consumption. It was hypothesized that optimizing the circulation in high risk patients before surgery would reduce cardiovascular stress and as an effect reduce mortality and morbidity. This hypothesis was evaluated in several randomized clinical trials.

The first trial on hemodynamic optimization in high risk surgical patients was performed by Shoemaker et al. In this study, subjects included in the intervention group had hemodynamic target values based on the median values achieved by survivors of a previous observational study. Subjects were monitored using balloon-tipped pulmonary artery and radial artery catheters. This trial demonstrated a rather large reduction in both mortality and morbidity (protocol mortality 4%, control 38%). Regarding the methodology several pitfalls and shortcomings of this trial should be mentioned; treatment protocols were not clearly mentioned, the control group did not receive standardized treatment and the study was not blinded.

To address these concerns Boyd et al. executed a subsequent trial. In this study both control and intervention group were treated with strict protocols. A reduction of both mortality and morbidity was shown in the intervention group. Pearse et al. also showed a reduction in morbidity and hospital stay in high risk patients undergoing major vascular or abdominal surgery. In this study, patients that were included in the treatment group received hemodynamic optimization based on the DO2, measured with lithium indicator dilution and pulse power cardiac output. Hemodynamic optimization was started and continued after surgery. The objective was to attain an oxygen delivery of at least 600 ml/min/ m2. No difference in mortality was found between the hemodynamic optimization group and the control group. A similar study on hemodynamic optimization in high risk surgery patients was interrupted because subjects included in the control group displayed a significant higher mortality. Several other randomized controlled trials with similar design and treatment protocols were executed. Yu et al and Wilson at al. both reported favorable outcomes in high risk surgical patients receiving hemodynamic optimization. Not all randomized studies showed a clear effect on mortality and morbidity. The multicenter study performed by Sandman et al showed no significant differences in mortality and morbidity. One of the potential explanations for this finding is the lack of a strict protocol. In stead patients were treated according to a guideline. Two other studies investigated the role of a fixed dose dopexamine on the outcome of surgical patients. Neither study showed a significant effect on mortality and morbidity. The results of hemodynamic optimization are likely to be better when treatment is tailored to the requirements of the individual patient. Several reviews and meta-analysis performed showed interventions aimed at hemodynamic optimalization in high risk surgical patients to reduce both mortality and morbidity.

Recently a non invasive cardiac output monitoring device; the FloTrac / Vigileo monitoring system was introduced. The system uses arterial wave form to calculate stroke volume. Use of this device has shown to reduce perioperative morbidity in the high risk population requiring surgery.

Fast track surgery

Danish surgeon Henry Kehlet developed a so-called fast track recovery multimodal programme. The programe incorporates preoperative, intraoperative and postoperative evidence-based techniques that optimize patient outcomes. Results of fast track programs have shown; fewer complications, a reduction in costs, a reduction in hospital length of stay, quicker return to work and normal activities.

The program includes several aspect of the perioperative treatment; Hypothermia has a negative effect on a patients stress response. Therefore during surgery body temperature should be controlled. Previous studies have demonstrated a positive relation between body temperature control and postoperative wound infections. Anesthesia that reduces surgical stress will contribute to the patients recovery. The use of neuraxial blockade and the use of epidural anesthesia has been shown to reduce the patients stress response. Postoperative pain is an important factor in the recovery of the patient. Efficient pain control encompassing thoracic epidural anaesthesia and non-opoid pain management has been demonstrated to reduce hospital stay. Furthermore pre-operative counselling of the patient, early postoperative feeding and mobilisation have demonstrated to reduce hospital length of stay and patient satisfaction.

This study aims to introduce a specialized clinical pathway (Optimal Track) for the perioperative management of the high risk surgical patient. In this pathway fast-track surgery principles and perioperative hemodynamic monitoring and optimization are combined. By applying this approach we aim to reduce mortality and morbidity in this group of patients. As a consequence of this reduction we expect a shortened postoperative recovery and an improved quality of life in these patients.

To date, no study has addressed the combined impact of a fast-track principles and perioperative hemodynamic monitoring and optimization on high risk surgical patients.

Study objective

To investigate the feasibility of the introduction of a specialized clinical pathway (Optimal Track) for the high risk surgical patient. In this pathway high risk surgical patients will receive treatment according to fast-track principles. Furthermore, patients will be admitted to a perioperative care unit for perioperative haemodynamic monitoring and if necessary optimization.

Study design

An observational Pilot study

Intervention

Hemodynamic monitoring/ optimisation

Study burden and risks

Radial artery canulation may be complicated with arterial spasms. In this case the contra lateral radial artery will be selected. Furthermore, placement of a radial artery catheter may be complicated in rare instances with local infection or blockage of the artery. In cases of infection the radial canule will be removed. Blockage of the radial artery after placement or removal of the radial canule, will in general not lead to ischemia because of collateral circulation of the hand.

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

- IRIS Score >= 4
- patients that will undergo elective surgery
- acute admitted patients who need to undergo semi-acute surgery (surgery within 24 hours

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Exclusion criteria

- IRIS score < 4
- decision not to operate
- acute surgery (no time for pre-operative work-up)

Study design

Design

Study type: Interventional	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	26-09-2012
Enrollment:	50
Туре:	Actual

Medical products/devices used

Generic name:	Flotrac/ VigileoTM monitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	10-06-2011
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO	

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Date:	20-09-2013
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	24-11-2014
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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 CCMO

ID NL31546.094.10