Influence of early goal-directed therapy using arterial waveform cardiac output measurement in high-risk surgery.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24432

Source
Nationaal Trial Register

Brief title
EGDT trial

Health condition

early goal-directed therapy (EGDT)
cardiac output
arterial waveform analysis
high-risk surgery
abdominal surgery

Sponsors and support

Primary sponsor: Division of Vital Functions
University Medical Center Utrecht
Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

The primary outcome is a combined endpoint of the number of major complications within the first 30 days after surgery:

1. Mortality (any cause);

2. Cardiac arrest;

3. Myocardial infarction;

4. Pulmonary edema;

5. Stroke;

6. Prolonged mechanical ventilation (>24 hrs);

7. Pulmonary embolism;

8. Pneumonia;

9. Respiratory failure (requiring mechanical ventilation);

10. Acute kidney injury;

11. Anastomotic leak;

12. Re-operation;

13. Wound infection;

14. Sepsis.

These major complications are associated with an increased 30-day and long-term mortality.

Secondary outcome

1. The number of the following minor complications in the first 30 days:

A. Arrhythmia;

B. Deep venous thrombosis;

C. Urinary tract infection;

D. Prolonged ileus;

E. Herniation or other prolonged wound healing.

2. Length of hospital stay;

3. Length of stay in the ICU/PACU;

4. Length of post-operative mechanical ventilation;

5. Continuation of care at intermediate care units;

6. Number of ICU, PACU or intermediate care readmissions in the first 30 days;

7. Discharge destination;

8. Total amount of fluid administrated in the first 24 hours;

9. Amount of vasoactive support in the first 24 hours;

10. Mean urine output in the first 24 hours;

11. Hemodynamic parameters (CO, MAP) in the first 24 hours;

12. Laboratory investigations (serum lactate, ScvO2, ABG) in the first 24 hours;

13. Quality of life (1, 3, 6 and 12 months);

14. Cost-effectiveness (1, 3, 6 and 12 months);

15. Long-term outcome (morbidity and mortality after 3, 6 and 12 months).

Study description

Background summary

The majority of complications after surgery occurs in a minority of patients. EGDT has shown to improve outcome in this patient group, which is high-risk either because of the type of surgery or due to the presence of coexisting disease. However, safety concerns and practical issues associated with advanced hemodyamic monitoring limit the introduction of EGDT in routine practice. Arterial waveform analysis (AWA) provides easy, less invasive, continuous cardiac output measurement, and could therefore guide EGDT. A number of small single-center studies investigating AWA-based EGDT in high-risk surgery showed promising results. However, a multi-center trial in a large patient sample has not been performed yet. In the

presented study, we aim to determine whether EGDT, aimed at optimizing CO measured by AWA, improves outcome in high-risk, abdominal surgery. The study design is a multi-center, randomized controlled, clinical study. The study population concerns 542 patients undergoing elective, extended abdominal surgery with an increased risk of postoperative mortality and morbidity.

Study objective

EGDT reduces the incidence of major complications in high-risk, abdominal surgery.

Study design

The time points for the outcome measures are indicated above.

Intervention

In patients allocated to EGDT, cardiac output (CO) is continuously measured using arterial waveform analysis until discharge from the ICU or PACU, with a maximum of 24 hours. If CO decreases below a preset, age-dependent, threshold value, a therapy algorithm starts in order to increase CO above the threshold value. In this algorithm, stroke volume variation measurement and passive leg raising are used to guide the choice for fluids or vasoactive substances to increase CO.

Standard care group:

Patients assigned to standard care will be treated according to local routine, with the following conditions:

1. After induction of anesthesia and tracheal intubation, patients will be mechanically ventilated (volume control) with a fixed tidal volume of 8 ml?kg-1 (ideal body weight, IBW) throughout the procedure, adjusting respiratory rate to maintain normocapnia;

2. An arterial line, central venous line and urine catheter are placed;

3. Hypotension after induction is treated with cristalloids or colloids first, with a maximum of 500 ml. Ongoing hypotension is treated with continuous infusion of norepinephrine. Sudden, short-lasting hypotension is treated with phenylephrine, ephedrine, or cafedrine/theodrenaline, depending on local routine;

4. Transfusions will be applied according to the 4-5-6 rule.

Therapy is aimed at maintaining:

1. SpO2 >/= 95%;

2. MAP >/= 60 mmHg or 25% below baseline in case of preexisting hypertension;

3. Heart rate < 100?min-1 or 25% above baseline.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients undergoing the following elective operations, irrespective of their ASA status:

A. Esophagectomy;

B. Pancreaticoduodenectomy;

C. Open abdominal aorta aneurysm (AAA) repair;

D. Major abdominal resections for soft tissue malignancy, in which post-operative observation in the ICU or PACU is indicated.

2. Patients undergoing the following elective operations, with ASA physical status III or IV:

A. Gastrectomy;

B. Colorectal resections for carcinoma;

C. Other extended upper or lower abdominal surgery for which post-operative observation in the ICU of PACU is indicated.

Exclusion criteria

1. Patients in which cardiac output measurement is indicated;

2. Age < 18 years;

3. Cardiac arrhythmias (atrial fibrillation or flutter, ventricular tachycardia);

4. Emergency surgery;

5. Contraindication for passive leg raising in the entire postoperative period.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	09-04-2012
Enrollment:	542
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-04-2012

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44010
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3228
NTR-old	NTR3380
CCMO	NL32416.041.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON44010

Study results

Summary results
N/A