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

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To determine whether early goal-directed therapy, aimed at optimizing cardiac output measured by arterial waveform analysis, improves outcome in high-risk, abdominal surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON44010

Source
ToetsingOnline

Brief title
EGDT in high-risk surgery

Condition

- Gastrointestinal therapeutic procedures

Synonym
high-risk surgery

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiac output, early goal-directed therapy, preload

Outcome measures

Primary outcome

The primary endpoint is the number of major complications in the first 30 days

after the operation.

Secondary outcome

Secundary outcome parameters are other complications, length of hospital and

ICU/PACU stay, the total amount of fluid and inotropics administrated, and

vital functions during surgery and in the OR and ICU/PACU.

Study description

Background summary

Early goal-directed therapy (EGDT) to optimize tissue oxygen delivery has shown to improve outcome in high-risk surgery. However, difficulty in the practical conduct of advanced hemodynamic monitoring limits the introduction of EGDT in routine practice. The PiCCO and Vigileo systems provide easy, minimal invasive, continuous cardiac output measurement using arterial waveform analysis, and could therefore guide EGDT.

Study objective

To determine whether early goal-directed therapy, aimed at optimizing cardiac output measured by arterial waveform analysis, improves outcome in high-risk, abdominal surgery.

Study design

Multi-center, randomized controlled, clinical study.

Intervention

Early goal-directed therapy, based on stroke volume variation measurement and passive leg raising, guiding fluid and inotropic therapy to keep cardiac output above a preset, age-dependent threshold value.

Study burden and risks

In the intervention group, cardiac output, and stroke volume variation are measured with PiCCO or Vigileo. These systems use the arterial and/or central venous lines that are routinely placed in high-risk surgical patients. Treatment with fluid challenges and inotropic support, is routine practice in the peri-operative period in high-risk surgery. As a result, the EGDT algorithm used in this study is not associated with an increased burden to health.

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

Included will be patients undergoing the following elective operations, irrespective of their their ASA classification:
- esophagectomy
- pancreaticoduodenectomy
- open abdominal aorta aneurysm (AAA) repair
- major abdominal resections for soft tissue malignancy, in which post-operative observation in the ICU or PACU is necessary
In addition, patients with ASA physical status III or IV undergoing the following operations are included, if post-operative observation in the ICU of PACU is necessary:
- gastrectomy
- colorectal resections for carcinoma
- other extended upper or lower abdominal surgery

Exclusion criteria

Exclusion criteria are:
- age < 18 years
- cardiac arrhythmias
- emergency surgery
- 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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-05-2012
Enrollment:	542

Type:	Actual

Medical products/devices used

Generic name:	cardiac output monitor (PiCCO and Vigileo)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-03-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-03-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-03-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-02-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-09-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24432
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL32416.041.10
OMON	NL-OMON24432