Personalized hemodynamic management targeting preoperative baseline cardiac index in high-risk patients having major abdominal surgery: the international multicenter randomized PELICAN trial

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To investigate whether personalized hemodynamic management targeting baseline cardiac index reduces the incidence of a composite outcome of acute kidney injury, acute myocardial injury, non-fatal cardiac arrest, severe infectious complications, and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON57190

Source
ToetsingOnline

Brief title
PELICAN

Condition

- Other condition

Synonym
anesthesiology, major abdominal surgery

Health condition

grote buik operaties

Research involving
Human

Sponsors and support

Primary sponsor: University Medical Center Hamburg-Eppendorf
Source(s) of monetary or material Support: Baxter,Baxter (Deerfield;IL;USA)

Intervention

Keyword: High risk patients, major abdominal surgery, Personalized hemodynamic management, preoperative cardiac index

Outcome measures

Primary outcome

Collapsed composite endpoint (*any event versus none*) of acute kidney injury,

acute myocardial injury (including myocardial infarction), non-fatal cardiac

arrest, severe infectious complications, and death within 7 days after surgery.

Secondary outcome

* Incidence of the composite primary outcome within 3 days after surgery

* Incidences of each of the individual components of the primary outcome within

3 and 7 days after surgery

* Individual incidences of fever, respiratory infection, neurological

infection, urinary system infection, colitis or infection with Clostridium

difficile, endometritis, surgical site infection, deep incisional surgical site

infection, organ or space surgical site infection, unknown infection with

pathogenic organisms in tissue or fluid, and sepsis within 7 days after surgery

* Collapsed incidence and individual incidences of need for renal replacement

therapy, myocardial infarction, non-fatal cardiac arrest, and death within 30

days and 90 days after surgery

* Time-to-event endpoint with the event *transfer from intensive care unit to

normal ward* within 90 days after surgery

* Time-to-event endpoint with the event *hospital discharge* within 90 days

after surgery

* Incidence of unplanned hospital re-admission within 30 days after surgery

Study description

Background summary

Postoperative mortality within 30 days after surgery is around 2% in patients having major noncardiac surgery in Europe and the USA. In fact, if the first 30 days after surgery were considered a disease, it would be the third leading cause of death globally. Postoperative deaths are a consequence of postoperative organ injury and complications - including acute myocardial injury, acute kidney injury, and severe infectious complications. To avoid postoperative deaths, it is thus crucial to reduce postoperative organ injury and complications.
A single-center pilot trial suggests that using individualized cardiac index targets during surgery may reduce postoperative organ injury and complications compared to routine hemodynamic management. However, large robust trials investigating the effect of personalized hemodynamic management targeting preoperative baseline cardiac index on postoperative complications are missing.

We, therefore, propose a multicenter randomized trial to test the hypothesis that personalized hemodynamic management targeting preoperative baseline cardiac index reduces the incidence of a composite outcome of acute kidney injury, acute myocardial injury, non-fatal cardiac arrest, severe infectious complications, and death within 7 days after surgery compared to routine hemodynamic management in highrisk patients having major abdominal surgery.

Study objective

To investigate whether personalized hemodynamic management targeting baseline cardiac index reduces the incidence of a composite outcome of acute kidney injury, acute myocardial injury, non-fatal cardiac arrest, severe infectious complications, and death within 7 days after surgery compared to routine hemodynamic management in high-risk patients having major abdominal surgery.

Study design

This is an international multicenter randomized controlled blinded interventional clinical trial.

Intervention

In patients assigned to personalized hemodynamic management, intraoperative cardiac index will be maintained at least at the preoperative baseline cardiac index. Patients assigned to personalized hemodynamic management will receive balanced crystalloids at a baseline infusion rate of 6 mL kg-1 h-1 and additional 500 mL fluid boluses (either colloid or crystalloid at the discretion of the attending physician) and dobutamine according to the treatment algorithm to maintain intraoperative cardiac index above the individual preoperative baseline value measured just before surgery. Mean arterial blood pressure will be maintained above 65 mmHg. The study intervention will start at the beginning of surgery and will end at the end of surgery.

Study burden and risks

Time-investment of approximatly 70-120 minutes in total, with very limited risks (in rare occasions additional bloodsampling) and a benefit of less expected risk on complications when in intervention group.

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

Consenting patients >=45 years who are scheduled for elective major abdominal surgery under general anesthesia that is expected to last >=90 minutes AND who have >=1 of the following high-risk criteria:
* Exercise tolerance <4 metabolic equivalents as defined by the guidelines of the American College of Cardiology/American Heart Association
* Renal impairment (serum creatinine >=1.3 mg dL-1 or estimated glomerular filtration rate <90 mL min-1 (1.73 m2)-1 within the last 6 months)
* Coronary artery disease
* Chronic heart failure (New York Heart Association Functional Classification >=II)
* Valvular heart disease (moderate or severe)
* History of stroke
* Peripheral arterial occlusive disease (any stage)
* Chronic obstructive pulmonary disease (any stage) or pulmonary fibrosis (any stage)
* Diabetes mellitus requiring oral hypoglycemic agent or insulin
* Immunodeficiency due to a disease (e.g., HIV, leukemia, multiple myeloma) or therapy (e.g., immunosuppressants, chemotherapy, radiation, steroids [above Cushing threshold])
* Liver cirrhosis (any Child-Pugh class)
* Body mass index >=30 kg m-2
* History of smoking within two years of surgery
* Age >=65 years
* Expected anesthesia duration >=180 minutes
* B-type natriuretic peptide (BNP) >80 ng/L or N-terminal B-type natriuretic peptide (NT-proBNP) >200 ng/L within the last 6 months

Exclusion criteria

* Emergency surgery
* Planned surgery: nephrectomy, liver or kidney transplantation surgery

* Status post transplantation of kidney, liver, heart, or lung
* Sepsis (according to current Sepsis-3 definition)
* American Society of Anesthesiologists physical status classification V or VI
* Pregnancy
* Impossibility to perform cardiac index monitoring using the Starling Fluid Management System (Baxter, Deerfield, IL, USA)
* Current participation in another clinical trial of a treatment with a similar biological mechanism or primary outcome measure

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2023
Enrollment:	145
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	13-08-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL84900.042.23
Other	NTC05648279