Prediction of complications after major gastrointestinal surgery with machine learning and point of care ultrasound: an observational cohort study.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON53240

Source
ToetsingOnline

Brief title
AI_PLUS

Condition

- Other condition

Synonym
perioperative complications and fluid tolerance.

Health condition

perioperatieve complicaties en vochthuishouding/hypotensie

Research involving

Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Fluid tolerance, Machine Learning, Major gastrointestinal surgery, Point of Care Ultrasound

Outcome measures

Primary outcome

The main study endpoint is a machine learning framework based on the hemodynamic profile to predict major complications, especially cardiovascular/pulmonary instability, including, sepsis and septic shock. Data from the ClearSight will be used to collect non-invasive arterial pressure waveforms. point of care ultrasound of heart, lungs and abdominal veins, and clinical data from the electronic medical record will be collected

Secondary outcome

point of care ultrasound of heart, lungs and abdominal veins, and clinical data from the electronic medical record will be collected. In a subgroup of 40 patients RAAS levels and portal blood samples will be analysed.

Study description

Background summary

Major complications occur frequently in patients after major gastrointestinal surgery. Changes in patients physiology often precedes deterioration and early detection of these changes may improve outcomes. The hemodynamic profile of these patients may hold information for the prediction of deterioration and

the optimal choice of resuscitation therapy.
In addition, point of care ultrasound can be used to assess fluid responsiveness and fluid intolerance. We hypothesise that a machine learning algorithm alongside point of care ultrasound can predict deterioration and determine whether an intervention with fluids or vasopressors is the optimal choice in each individual setting.

Study objective

The primary aim of this study is to develop a machine learning framework to predict major complications after major gastro-intestinal surgery. Secondary aims include combining this framework with point of care ultrasound to determine the best initial resuscitative strategy; and to determine which ultrasound parameters are best predictive of fluid intolerance. Furthermore if RAAS is more active after liver resection.

Study design

Single centre observational cohort study

Study burden and risks

There are no additional risks or benefits associated with participation. There are no investigational devices used in this study. There are no additional risks associated with the use of the CS/EV1000/HemoSphere monitor other than described in the instructions for use. There are also no or very small risks associated with the other study procedures, including ultrasound.

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

>=18 years of age.
elective major gastrointestinal surgery: esophagectomy, gastrectomy, pancreactomy or major liver resection (3 segments or more).

Exclusion criteria

- no informed consent
- Patients with major cardiac shunts
- Patients with dialysis shunts or peritoneal dialysis
- Patients in whom POCUS is not possible or assessment of fluid status is unreliable e.g. BMI> 40, pulmonary fibrosis.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-11-2023
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	12-10-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL84107.018.23