Biomarkers to guide perioperative management and improve outcome in high-risk surgery

Published: 02-06-2021
Last updated: 21-12-2024

To describe the perioperative biomarker response in surgical patients with and without a postoperative complication.To construct a preoperative and postoperative prediction model for postoperative complications to improve risk stratification and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON54308

Source
ToetsingOnline

Brief title
BIG PROMISE

Condition

- Cardiac therapeutic procedures

Synonym
Adverse event, complication

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: Roche Diagnostics

Intervention

Keyword: biomarker, complications, high-risk surgery

Outcome measures

Primary outcome

Main study parameters are levels of PCT, CRPhs, IL-6, GDF-15, sFLT, NT-proBNP, cTNThs, CysC and NGAL.

The primary outcome parameter is a major postoperative complication (within 30 days of surgery) and includes surgical site infection, pneumonia, sepsis, acute kidney injury, major adverse cardiac events and all-cause mortality

Secondary outcome

Secondary study parameters are levels of Hb, Ht, MCV, RDW, reticulocytes, thrombocytes, leucocytes, MPV, urea, creatinine, sodium, potassium, chloride, calcium, phosphate, magnesium, ASAT, ALAT, LDH, ALP, gamma GT, bilirubin, CK, albumin, glucose, Cholesterol, Triglycerides, HDL-cholesterol, LDL-cholesterol, serum iron, ferritin, transferrin saturation. vitamin D, TSH, FT4, igf-1, SHBG.

Secondary study endpoints are:

Duration of ICU stay

ICU readmission

ICU mortality

Failure to rescue

Duration of hospital stay

Hospital readmission

Hospital mortality

30-day mortality

120-day mortality

1-year mortality

2-year mortality

Days alive and out of the hospital at 120 days

Myocardial injury

Change in disability (measured with the World Health Organization Disability

Assessment Schedule (WHODAS 2.0, 12-item version)

Study description

Background summary

There is an unmet need in perioperative medicine for adequately powered studies that systematically target the association between perioperative biomarker responses and postoperative complications. Currently, there is insufficient knowledge of the pathophysiology of postoperative complications and a lack of objective and reliable information that can be used for risk stratification and guide treatment decisions. In addition, a scarcity exists of systematically collected high quality outcome data in the surgical population undergoing high-risk procedures. Biomarkers, both new and existing, can provide objective molecular information to better understand the pathophysiology of postoperative complications and can help to improve risk stratification and facilitate health care improvements that aim to reduce the number of adverse events in high-risk surgical patients.

Study objective

To describe the perioperative biomarker response in surgical patients with and without a postoperative complication.
To construct a preoperative and postoperative prediction model for postoperative complications to improve risk stratification and guide treatment decisions in high-risk surgical patients.

Study design

Prospective observational multicentre cohort study

Study burden and risks

In each patient five blood samples will be drawn for analysis. Most of the blood samples are drawn simultaneously with routine perioperative laboratory testing, which is common in this study population. In case a patient is admitted to the Intensive Care Unit blood samples will be collected using an arterial line. If an arterial line is not available, venipuncture will be performed by a laboratory nurse according to standard operating procedures. A venipuncture will be performed simultaneously with routine laboratory testing that are a part of perioperative care, if applicable. The risks of a venipuncture are minimal. They include discomfort at the puncture site, bruising or swelling at the puncture site, or an infection of the skin. Patients are asked to fill out a questionnaire pre-and postoperatively (5-10 minutes for each questionnaire).

Contacts

Public
Amphia Ziekenhuis

Molengracht 21
Breda 4818 CK
NL
Scientific
Amphia Ziekenhuis

Molengracht 21
Breda 4818 CK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Cardiac surgery (isolated coronary artery bypass grafting or combined with single valve surgery, isolated single valve surgery)
- Gastrointestinal surgery (colorectal, pancreatic, gastric surgery, hyperthermic intraperitoneal chemotherapy).
- Vascular surgery (open and endovascular aortic surgery, peripheral vascular surgery)
- Lung surgery (pneumonectomy,(bi)(sleeve)lobectomy or segmentectomy)

Exclusion criteria

- Age < 18 years - Pregnancy - Emergent surgery - No informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-10-2021
Enrollment:	4819
Type:	Actual

Ethics review

Approved WMO

Date:	02-06-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-11-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-03-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-06-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-08-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-12-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-02-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-06-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	06-11-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-11-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL74076.100.20