Changes in host gene expression to differentiate between systemic inflammation and infection after major surgery (PAX study)

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Primary Objective: To study the early diagnostic performance of specific gene signatures for differentiation of patients having postoperative infection (A1) or sepsis (A2) from non-infected patients having postoperative SIRS (B1) and non-infected...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON56862

Source
ToetsingOnline

Brief title
PAX study

Condition

- Bacterial infectious disorders

Synonym
infection, Sepsis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: Presymptom Health Limited,Presymptom Health Limited (www.presymptom.com)

Intervention

Keyword: Infection, Inflammation, Transcriptomics

Outcome measures

Primary outcome

Postoperative infection

Secondary outcome

SIRS, sepsis

Study description

Background summary

Despite preventive measures, a considerable number of surgical patients suffer from a postoperative infection. The incidence of postoperative infection exceeds 30% in patients undergoing major noncardiac surgery such as pancreatic or esophageal cancer. Postoperative infections are associated with poor health and death after surgery, and increased healthcare costs. Diagnosis of surgical patients with an infection at an early stage would enable prompt intervention, but effective biomarkers are currently lacking.
Surgical trauma activates the innate immune system and triggers a systemic inflammatory response syndrome (SIRS) in up to 50% of patients over the course of the first 7 postoperative days. This increases risk for infection as well as complicates its early diagnosis, which now relies primarily on clinical features and unspecific biomarkers of inflammation (e.g. C-reactive protein, leucocyte count, fever, tachycardia). Differentiation between SIRS and postoperative infection is thus challenging, and the diagnostic uncertainty that results from this may cause delays in interventions to prevent a patient from deteriorating to organ dysfunction or eventually death.
Changes in host gene expression may provide additional diagnostic information for postoperative infection. A recent study identified infection in surgical patients in advance of clinical diagnosis, and reliably differentiated infected from non-infected patients, by using blood leukocyte transcriptomics.

Study objective

Primary Objective: To study the early diagnostic performance of specific gene signatures for differentiation of patients having postoperative infection (A1) or sepsis (A2) from non-infected patients having postoperative SIRS (B1) and non-infected patients having an uncomplicated postoperative course (B2)

Study design

Multicenter observational cohort study

Study burden and risks

In each patient blood samples will be drawn for analysis on the following time points: after induction for anaesthesia, directly postoperative and on postoperative day 1 - 7. For each sample 2.5 ml of blood is taken. In a total of 9 samples this results in a cumulative volume of 22.5 ml. Whenever possible, blood samples will be drawn simultaneously with routine perioperative laboratory testing. In case of admission to the Intensive Care Unit blood samples will be collected using an arterial line. There are no direct risks or benefits for patients included in the study.

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

A subject must meet all of the following criteria: Age >18 years, major noncardiac surgery with infection risk >20% (e.g., pancreatic surgery, hyperthermic intraperitoneal chemotherapy (HIPEC) surgery, colon resection).

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: Age <18 years, emergency surgery, inability to provide informed consent.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-12-2004
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	04-07-2024
Application type:	First submission
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
ClinicalTrials.gov	NCT06116656
CCMO	NL85583.100.24