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Monitoring inflammation during cancer surgery using heart and brain signals

Submission date
07/05/2025

Recruitment status
No longer recruiting

Registration date
09/07/2025

Overall study status
Completed

Last Edited
09/07/2025

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Major surgeries, such as those for abdominal or gynaecological cancers, can cause inflammation in the body. This inflammation is a natural response to injury, but in some patients it can become too strong and lead to serious complications like organ damage, confusion, or even death. Currently, doctors do not have a good way to monitor this inflammation in real-time during surgery.

This study aims to develop a new way to monitor inflammation using signals from the heart (heart rate variability or HRV) and the brain (electrical brain activity, recorded as EEG). By combining these two types of data, researchers hope to find a non-invasive method to predict when a patient might be developing harmful levels of inflammation. This could lead to faster and more targeted care.

Who can participate?
Adults (18 years and older) who are scheduled to undergo abdominal or gynaecological cancer surgery, with a special heated chemotherapy treatment called HIPEC, can participate. People cannot take part if they:
- Cannot give informed consent,
- Have a pacemaker or defibrillator,
- Have recently had a heart attack or cardiac arrest,
- Or have a known allergy to the adhesive patches used for the monitoring equipment.

What does the study involve?
Participants will have their heart and brain activity monitored during surgery using a device called CoreSys One. This device uses small sticky pads placed on the forehead and chest. These measurements do not cause pain and are similar to standard hospital monitoring.

Blood samples will also be taken at regular intervals during surgery. These are usually taken as part of standard care, but samples will be used to study the inflammation levels.

The surgery, anaesthesia, and recovery will follow standard hospital procedures. The only change is the extra monitoring and use of blood samples.

What are the possible benefits and risks of participating?
There is no direct benefit to participants. However, the information collected could help future patients by leading to better ways to monitor and treat inflammation during surgery.
Risks are minimal. The monitoring device is non-invasive and safe. There is a small chance of skin irritation from the sticky pads. Patients who are allergic to these will not be included.

Where is the study run from?
The study is being run at the University Medical Center Groningen (UMCG) in the Netherlands.

When is the study starting and how long is it expected to run for?
May 2023 to June 2025.

Who is funding the study?
The study is supported by the Department of Anesthesiology at UMCG and the medical technology company Coresys Health, which provides the monitoring equipment and technical support. Additional external funding may be sought.

Who is the main contact?
Dr. Gertrude Nieuwenhuijs-Moeke
Assistant Professor of Anesthesiology
University Medical Center Groningen (UMCG)
Email: g.j.nieuwenhuijs-moeke@umcg.nl

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Gertrude Nieuwenhuijs-Moeke

Contact details
Hanzeplein 1
Groningen
Netherlands
9713EZ
+31 (0)503616161
g.j.nieuwenhuijs-moeke@umcg.nl

Additional identifiers

Protocol serial number
METC 2023/030

Study information

Scientific Title
Perioperative systemic inflammatory response syndrome monitoring with electroencephalogram and heart rate variability

Acronym
PRISM

Study objectives
Assess the ability to predict and monitor the perioperative inflammatory response and/or systemic inflammatory response syndrome (SIRS) with a non-invasive method using heart rate variability (HRV) parameters combined with EEG-derived parameters

Ethics approval required
Ethics approval not required

Ethics approval(s)
The medical ethics review board of the University Medical Center Groningen (METc UMCG) determined it is an nWMO study and does not require ethics approval. Ref: METC 2023/030

Primary study design
Observational

Study design
Prospective cohort study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Patients scheduled for an abdominal/gynaecological oncological surgical procedure +/- combined with hyperthermic intraperitoneal chemotherapy (HIPEC)

Interventions
Participants in this study are adult patients scheduled for abdominal or gynaecological cancer surgery, with or without heated chemotherapy (HIPEC). After giving informed consent, they will be monitored during their surgery using a non-invasive device called CoreSys One. This device records electrical signals from the heart (ECG for heart rate variability) and brain (EEG for brain activity) using small adhesive sensors placed on the chest and forehead.

In accordance with standard surgical care, blood samples, collected at specific timepoints during surgery, will be used to measure levels of inflammation.

Total duration of observation per participant is from the start of surgery to the end of surgery, approximately 3 to 8 hours depending on the procedure. There is no follow-up after surgery for this study.

Intervention Type
Other

Primary outcome(s)
Inflammation levels are measured using cytokine concentrations (e.g. IL-6, TNF-α) in blood samples taken at baseline (before surgery), and every 30 minutes during surgery (until the end of surgery). These are compared with:
Heart rate variability (HRV) parameters (e.g. LF, HF, RMSSD) and
EEG parameters (e.g. Spectral Edge Frequency, Burst Suppression)

Key secondary outcome(s)
1. Impact of anaesthetic type (propofol vs sevoflurane) on HRV and EEG parameters — measured during surgery using the CoreSys One device.
Device usability:
2. User experience and technical performance of the CoreSys One device — assessed through qualitative feedback forms completed by clinical staff post-surgery.
Clinical outcomes:
3. Organ dysfunction: Presence of acute kidney injury (AKI), postoperative delirium (POD), acute lung injury (ALI), perioperative myocardial injury (P-AMI) — extracted from medical records within 48 hours after surgery.
4. Length of ICU stay — recorded in days from medical records.
5. Length of hospital stay — recorded in days from medical records.
6. 28-day mortality — assessed through patient follow-up in hospital records.
7. Surgical complications graded using Clavien-Dindo classification (CD ≥ 3) — assessed during hospital stay.

Completion date
01/06/2025

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Scheduled for an abdominal/gynaecological oncological surgical procedure +/- combined with HIPEC

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
75

Key exclusion criteria

1. Inability to provide informed consent
2. Allergy to adhesive electrodes
3. Presence of a pacemaker/ICD
4. Recent cardiopulmonary arrest
5. Cardiac arrhythmias
6. Atrial fibrillation

Date of first enrolment
10/05/2023

Date of final enrolment
01/06/2025

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
Hanzeplein 1
Groningen
Netherlands
9713GZ

Sponsor information

Organisation
University Medical Center Groningen

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Not defined

Funder Name
umcg

Funder Name
umcg

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated during the current study will be available upon request from Gertrude Nieuwenhuijs-Moeke (g.j.nieuwenhuijs-moeke@umcg.nl)

IPD sharing plan summary
Available on request