

# Monitoring inflammation during cancer surgery using heart and brain signals

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<b>Registration date</b> 09/07/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/07/2025	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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  
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University Medical Center Groningen (UMCG)  
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## Contact information

### Type(s)

Public, Scientific, Principal investigator

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### 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

## Study design

Prospective cohort study

## Primary study design

Observational

## 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- $\alpha$ ) 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  $\geq$  3) — assessed during hospital stay.

### **Completion date**

01/06/2025

## **Eligibility**

### **Key inclusion criteria**

1. Aged  $\geq$ 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