

# Effect of wearable continuous vital signs measurements on general wards length of stay

<b>Submission date</b> 13/12/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/12/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/01/2024	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Surgical complications are unfortunately still common. For several years now, wearable, wireless devices for continuous measurements of vital signs become available instead of intermittent, manual measurements. This makes it possible to detect clinical deterioration earlier, potentially improving care outcomes. The study aims to determine the effect of continuous monitoring of vital signs in the ward on length of hospital stay in colorectal, pancreatic, and liver surgery.

### Who can participate?

Patients undergoing colorectal, pancreatic, or liver resections.

### What does the study involve?

Patients wear a wearable sensor for continuously measuring heart rate and respiratory rate after surgery during their hospital stay.

### What are the possible benefits and risks of participating?

Possible benefit for patients is that clinical deterioration is earlier detected and treated. There are no risks in participating.

### Where is the study run from?

Isala, Zwolle (Netherlands)

### When is the study starting and how long is it expected to run for?

February 2020 to July 2022

### Who is funding the study?

Isala Innovation & Science Funds (Netherlands)

### Who is the main contact?

JPL Leenen, MSc, [j.p.l.leenen@isala.nl](mailto:j.p.l.leenen@isala.nl)

## Contact information

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Scientific

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

ID1

## Study information

**Scientific Title**

Effectiveness of wireless wearable continuous vital signs monitoring on wards: a prospective single-arm study with historical control group

**Acronym**

Ef-CoMoViSi trial

**Study objectives**

Continuous monitoring of vital signs reduces length of stay than intermittent vital signs monitoring on the general ward

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 17/12/2021, METC Isala (Dr. van Heesweg 2, Building M [Mondriaan], room 0.25, Mailbox 10400, Zwolle, 8000 GK, Netherlands; +31 (0)88 624 30 82; metc@isala.nl), ref: 20211114

**Study design**

Prospective single-arm study with historic control group

**Primary study design**

Observational

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Vital signs of surgical patients undergoing colorectal, liver and pancreatic resections

**Interventions**

During the pre-admission consult by telephone, study information is given by the nurse and informed consent was provided by the patient. When patients are admitted and underwent surgery, the wearable sensor (Philips Healthdot) for continuous monitoring of vital signs is attached by the nurse. Vital signs are intermittently measured and monitored according to the Modified Early Warning Score protocol (once daily). Until discharge, the patient wears the sensor and vital sign trends are reviewed six times a day by the nurse and once a day by the physician. When trends deviated, necessary actions were taken. When the patient was discharged, the sensor was detached. After one month, clinical outcomes were registered based upon the patient file.

The control group was a historical cohort of patients included through the EMR.

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Wearable vital signs monitoring (Philips Healthdot, Philips, Eindhoven, NL)

**Primary outcome(s)**

Length of stay (in days) measured using the admission and discharge date in days from the Electronic Medical Record (EMR) at 30 days after discharge.

## **Key secondary outcome(s)**

1. RRT calls measured using reports in the EMR at 30 days after discharge.
2. House-officer calls measured using reports in the EMR at 30 days after discharge
3. Unplanned ICU admission measured using reports in the EMR at 30 days after discharge
4. ICU length of stay measured using reports in the EMR at 30 days after discharge
5. Mortality measured using reports in the EMR at 30 days after discharge
6. Readmission measured using reports in the EMR at 30 days after discharge
7. Unplanned diagnostics measured using reports in the EMR at 30 days after discharge
8. Discharge destination measured using reports in the EMR at 30 days after discharge
9. Nursing care after admission measured using reports in the EMR at 30 days after discharge
10. Days alive at home (DAH30) measured using reports in the EMR at 30 days after discharge
11. Complication rate according Clavien-Dindo classification using reports in the EMR at 30 days after discharge
12. Failure-to-rescue measured using reports in the EMR at 30 days after discharge

## **Completion date**

01/07/2022

## **Eligibility**

### **Key inclusion criteria**

1. Expected length of stay  $\geq 2$  days
2. Admitted to the surgical ward of Isala
3. Admission indication: Colorectal, Liver or Pancreatic resection

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

Not being able to provide informed consent

### **Date of first enrolment**

01/01/2022

### **Date of final enrolment**

01/07/2022

## **Locations**

### **Countries of recruitment**

Netherlands

### Study participating centre

Isala

Dr. van Heesweg 2

Zwolle

Netherlands

8025 AB

## Sponsor information

### Organisation

Isala

### ROR

<https://ror.org/046a2wj10>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Isala

## Results and Publications

### Individual participant data (IPD) sharing plan

The anonymized datasets generated during and analysed during the current study will be available upon request from JPL Leenen ([j.p.l.leenen@isala.nl](mailto:j.p.l.leenen@isala.nl))

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		17/01/2024	19/01/2024	Yes	No
<a href="#">Participant information sheet</a>	version 1	01/04/2021	21/12/2021	No	Yes