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

**Submission date**
13/12/2021

**Recruitment status**
No longer recruiting

**Registration date**
24/12/2021

**Overall study status**
Completed

**Last Edited**
19/01/2024

**Condition category**
Surgery

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

## Contact information

**Type(s)**
Scientific

**Contact name**
Mr Jobbe Leenen

**ORCID ID**
https://orcid.org/0000-0001-7269-2892

**Contact details**
Dr. van Heesweg 2
Zwolle
Netherlands
8025 AB
+31 384241245
j.p.l.leenen@isala.nl

**Type(s)**
Scientific

**Contact name**
Dr Gijsbert Patijn

**ORCID ID**
https://orcid.org/0000-0001-8113-4171

**Contact details**
Dr. van Heesweg 2
Zwolle
Netherlands
8025 AB
+31 384244349
g.a.patijn@isala.nl

# Additional identifiers

**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

## Primary study design
Observational

## Study design
Prospective single-arm study with historic control group

## 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 ≥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)

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 17/01/2024 | 19/01/2024 | Yes | No |
| Participant information sheet | version 1 | 01/04/2021 | 21/12/2021 | No | Yes |