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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

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files (in Dutch)

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/02/2020

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

Age group
Adult

Sex
Both

Target number of participants

1027

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
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Sponsor information

Organisation
Isala

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Sponsor type
Hospital/treatment centre

Website
http://isala.nl

ROR
https://ror.org/046a2wj10

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Isala

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2023

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?
Participant information sheet	version 1	01/04/2021	21/12/2021	No	Yes
Results article		17/01/2024	19/01/2024	Yes	No