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A study of a wireless sensor (the Radius VSM biosensor) during surgery and recovery

Submission date
04/06/2024

Recruitment status
Recruiting

Registration date
26/07/2024

Overall study status
Ongoing

Last Edited
23/01/2026

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Closing the monitoring gaps for early warning of perioperative and early postoperative deterioration while allowing early mobilization is considered one of the main applications of telemonitoring, a sub-category of eHealth. Good reliability and accuracy of wearable biosensors in their estimates of vital signs are key in the use of telemonitoring at the surgical ward. The Radius VSM biosensor (Masimo, Irvine, CA, USA) has recently been developed for the continuous monitoring of vital parameters in-hospital and is one of the first that also enables non-invasive blood pressure measurements.

Research question: What is the clinical reliability and accuracy of continuous non-invasive telemonitoring of vital parameters using the Radius VSM biosensor during the perioperative and early postoperative period?

This study provides insight in the clinical reliability, accuracy and applicability of the Radius VSM biosensor for the continuous monitoring of surgical patients. This information will be used for the development of telemonitoring strategies for early detection and prevention of postoperative deterioration of surgical patients.

Who can participate?
Patients who were admitted to the surgical ward and planned for surgery. All participants were 18 years or older and had an expected hospital stay of at least 48 hours.

What does the study involve?
This is a single-center observational study in 50 surgical patients who wear the Radius VSM biosensor during surgery until hospital discharge. To get insight in the reliability and accuracy of the Radius VSM biosensor, measured values will be compared to measurements of validated peri- and postoperative monitoring devices used in usual care.

What are the possible benefits and risks of participating?
The burden of this study is low. Patients receive extra monitoring by wearing a wireless biosensor during their hospital admission and are asked to report on their pain and quality of recovery regularly. Patients are not expected to experience physical, psychological or mental

strain due to the monitoring. All measurements are safe and non-invasive. Patients will not directly benefit from the extra monitoring, since no interventions are applied in this pilot study.

Where is the study run from?
University Medical Center Groningen (Netherlands)

When is the study starting and how long is it expected to run for?
December 2023 to December 2028

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Marjolein Haveman, m.e.haveman@umcg.nl

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
202100026

Study information

Scientific Title
Clinical reliability, accuracy and applicability of continuous telemonitoring of vital parameters during the perioperative and early postoperative period using the Radius VSM biosensor: an observational study

Acronym
RECORD

Study objectives

Closing the monitoring gaps at the operating theatre and surgical ward, early warning of postoperative deterioration while allowing early mobilization is considered one of the main applications of telemonitoring, a sub-category of eHealth. Commercially available wearable biosensors use photoplethysmography (PPG) or single-lead ECG to derive data on heart rate, heart rate variability, respiratory rate, and blood oxygen saturation. However, evidence for continuous monitoring with wearable devices is lacking .

Good reliability and accuracy of wearable biosensors in their estimates of vital signs are key in overcoming the barriers for broad implementation of telemonitoring at the surgical ward. The Radius VSM biosensor (Masimo, Irvine, CA, USA) has recently been developed for the continuous monitoring of vital parameters in-hospital and is one of the first that also enables non-invasive blood pressure measurements. This allows calculation of a modified early warning score (MEWS), which might be one of the advantages of this monitor over other wearables. The aim of this study is to assess the clinical reliability, accuracy and applicability of data from continuous non-invasive telemonitoring of vital parameters using the Radius VSM biosensor during the perioperative and early postoperative period.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/12/2023, Ethical Committee University Medical Center Groningen (Hanzeplein 1, Groningen, 9713GZ, Netherlands; +31 6 55 25 76 00; nwmoloket@umcg.nl), ref: 202100026

Primary study design
Observational

Study design
Single-center observational study

Study type(s)
Other

Health condition(s) or problem(s) studied
Patients admitted at the surgical ward

Interventions
Patients receive standard care, and in addition will be wearing a wearable sensor for continuous monitoring of non-invasive blood pressure, heart rate, respiratory rate, temperature and oxygen saturation. No medical decisions will be made using data collected by the wearable sensors in this trial. In addition, patients are actively asked to report postoperative pain scores on a numeric rating scale (NRS) every 2 hours during daytime with their own smartphone

Intervention Type
Other

Primary outcome(s)
Reliability and accuracy
1. Presence (percent of time) of a continuous data-stream of vital parameters via the Masimo Radius VSM device: heart rate, blood pressure, oxygen saturation, respiration rate and skin temperature

2. Comparison of the numerical values of the Masimo Radius VSM versus vital parameter measurements from perioperative anesthetic monitoring and postoperative monitoring at the PACU

Key secondary outcome(s)
Clinical applicability
1. Data quality and data losses and how this is related to motion or physical activity
2. Vital parameters acquired during standard nursing rounds and MEWS data derived from rounds and computed by EMR
3. Patient reported pain scores and results from the daily QoR-15NL collected using RoQua (www.roqua.nl) and stored within the EMR
4. Incidence and moments of perioperative or postoperative complications
5. Incidence and moments of administration of (unexpected) drug therapy, e.g. i.v.-fluids, into tropics or antibiotics
6. Experiences of patients (satisfaction, barriers and potential benefits)

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Patients admitted to the surgical ward
2. Planned for surgery
3. 18 years or older
4. Expected hospital stay of at least 48 hours

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria

1. Mentally incapable of participation
2. Unable to wear wearable devices
3. Postoperative ICU admission
4. No smartphone
5. Ambulatory or day surgery

Date of first enrolment
01/11/2024

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
Hanzeplein 1
Groningen
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Sponsor information

Organisation
University Medical Center Groningen

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Available on request
m.e.haveman@umcg.nl

IPD sharing plan summary
Available on request