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Postoperative continuous telemonitoring at the surgical ward

Submission date
11/07/2023

Recruitment status
No longer recruiting

Registration date
03/11/2023

Overall study status
Ongoing

Last Edited
31/05/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Telemonitoring, a sub-category of eHealth, may play a role in the early detection of postoperative deterioration, lower workload for nurses and facilitate the migration of care towards home. Wearable sensors are available for the continuous monitoring of vital signs, including skin temperature, heart rate, respiratory rate, blood oxygenation, and activity parameters. It is still unknown, however, how to incorporate continuous telemonitoring in the perioperative trajectory of surgical patients. As a pilot for further trials, the aim of this study is to assess the feasibility and applicability of telemonitoring by continuous monitoring of vital signs and physical activity of patients at the post-anesthesia care unit (PACU) and a surgical ward.

Who can participate?
Patients aged 18 years or older admitted to the surgical ward and planned for surgery with an expected postoperative stay of 48 hours

What does the study involve?
During a period of 3 months patients receive standard care and wear two wearable sensors for continuous monitoring. No medical decisions will be made using the data collected by the telemonitoring devices.

What are the possible benefits and risks of participating?
The burden of this study is low. Patients receive extra monitoring by wearing two sensors during their postoperative hospital stay. Patients are not expected to experience physical, psychological or mental strain due to the monitoring. All measurements are safe and non-invasive.

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?
June 2021 to December 2025

Who is funding the study?
Stichting Lijf & Leven (Netherlands)

Who is the main contact?
1. Rianne van Melzen, r.van.melzen@umcg.nl
2. Marjolein Haveman, m.e.haveman@umcg.nl
3. Prof. Dr. Jean-Paul de Vries

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
202000231

Study information

Scientific Title
Postoperative continuous telemonitoring; an observational study

Acronym
TRUST

Study objectives
Telemonitoring may play a role in the early detection of postoperative deterioration, lower workload for nurses and facilitate the migration of care towards home. Wearable biosensors are available for continuous monitoring of vital signs, including temperature, heart rate, respiratory rate, blood oxygenation, and activity parameters. It is still unknown, however, how to incorporate continuous telemonitoring in the perioperative trajectory of surgical patients. The aim of this prospective, observational trial is to assess the feasibility and applicability of telemonitoring by continuous monitoring of vital signs and physical activity of patients at the post-anesthesia care unit (PACU) and a surgical ward.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/11/2021, Ethical Committee University Medical Center Groningen (Hanzeplein 1, Groningen, 9713 GZ, Netherlands; +31 (0)6 55 25 76 00; nwmoloket@umcg.nl), ref: 202000231, METc nr. 2021/440

Study design
Single-center observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Patients admitted to the surgical ward after surgery

Interventions
Patients receive standard care, and in addition will be wearing two wearable sensors for continuous monitoring of heart rate, respiratory rate, temperature and oxygen saturation. No medical decisions will be made using data collected by the wearable sensors in this trial. Patients wear the sensors during their postoperative hospital stay for up to 7 days.

1. The VitalPatch enabling (non-invasive) ECG-based measurements of heart rate (variability), respiration rate, oxygen saturation, body temperature, fall detection and physical activity (step count, and type of activity) at a frequency of once per second.
2. The Masimo Radius PPG sensor enabling (non-invasive) saturation-based measurement of heart rate, respiration rate, body temperature, and oxygen saturation at a frequency of once per minute.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
VitalPatch, Masimo Radius PPG sensor

Primary outcome measure
Feasibility for each sensor during the study period (stay at the surgical ward for a maximum of 7 days) assessed by the following measures:
1. Participation rate: number of patients willing to participate/complete the study protocol
2. Acceptability in terms of satisfaction about the logistics and wearing the sensor, measured by experiences of patients collected using a questionnaire before discharge and at the end of the study
3. Practicality by aspects of (tele)monitoring that involve the actual experience:
3.1. Compliance with the amount of days/hours that the sensor is worn
3.2. Time spent by nurses concerning telemonitoring versus vital parameter measurements in current practice, measured through daily evaluation form and by recording the time needed for intermittent measurements of vital signs manually
3.3. Experiences and recommendations of nurses, assessed with evaluation forms and interviews
3.4. Data quality: missing data, artefacts and reasons for data losses

Secondary outcome measures
Applicability (for each sensor) during the study period (stay at the surgical ward for a maximum of 7 days):
1. Continuous data stream of vital functions: heart rate, saturation, respiration rate, body temperature, daily step count, type of activity and fall detection

2. Measurements of vital signs in usual care from the electronic medical record
3. Comparison of the characteristics and quality from both wearable sensors will take place for the following outcomes: participation rate, acceptability, practicality, data quality and continuous data stream of vital functions
4. The following clinical and surgical data will be obtained via electronic medical records: age, gender, primary diagnosis, comorbidities, surgery date, procedure type, length of hospital stay, reported early warning scores, incidence and moments of postoperative complication (including falling), treatment, and incidence, moment and duration of unplanned readmission within 30 days after surgery.

Overall study start date
01/06/2021

Completion date
31/12/2025

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Total final enrolment
124

Key exclusion criteria
1. Mentally incapable of participation
2. Unable to wear wearable devices

Date of first enrolment
01/04/2022

Date of final enrolment

01/07/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
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Sponsor information

Organisation
University Medical Center Groningen

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Sponsor type
Hospital/treatment centre

Website
http://www.umcg.nl/EN

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Charity

Funder Name

Stichting Lijf en Leven

Alternative Name(s)
Lijf en Leven Foundation, Stichting Lijf & Leven

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Netherlands

Results and Publications

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

Intention to publish date
01/01/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from R. van Melzen (r.van.melzen@umcg.nl).

IPD sharing plan summary
Available on request