PJ-013483 FLAGSHIP Transitional Care Study 3

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27909

Source
Nationaal Trial Register

Brief title
TRICA

Health condition

Patients, scheduled for surgery e.g. bariatric and major surgery such as cytoreductive surgery and hyperthermic intraperitoneal chemotherapy (HIPEC), complex rectal surgery, esophagectomy and pancreatectomy.

Sponsors and support

Primary sponsor: Philips Electronics Nederland B.V., acting through Research, Eindhoven, NL
Source(s) of monetary or material Support: Category 3 funding by Philips Research

Intervention

Outcome measures

Primary outcome

The primary endpoint is to evaluate the sensitivity and specificity for the prediction of deterioration after surgery using the data calculated based on accelerometer and/or PPG

measurements.
The deterioration is primarily defined as complication according to Clavien Dindo classification grade II or higher. Complications are further assessed by the following events:
· Unplanned ICU admission
· Rapid Response Team (RRT) visit to patient
· Start of antibiotics
· Re-surgery
· Radiologic intervention such as abscess drainage
· Suppletion of erythrocytes, thrombocytes and Fresh Frozen Plasma
· Increase in early warning scores
· Readmission after discharge
· Death

Secondary outcome

• Agreement of the calculated heart rate and respiratory rate compared to the gold standard.
• Description of the extent of hampering in daily activities by both devices as assessed by the patients.

Study description

Background summary

In this study patients with elective surgery will wear two devices (HealthDot and Elan) after surgery in hospital and after discharge at home for up to 2 weeks (HealthDot) or 3 weeks (Elan). The HealthDot will measure breast motion by accelerometer and calculate heart rate, posture, activity and respiratory rate which are stored on the device as well as sent via LoRa network to Philips. The Elan device will measure PPG and accelerometer data which is transferred via an MSX (Monitoring Study boX) to Philips. The data collected will be used for algorithm development. Data will be analysed retrospectively and compared to readmission and adverse events to see if the events could have been predicted due to the collected data by the devices. No clinical decisions will be based on the measurements done during the study.

Study objective

Primary hypothesis
• The calculated heart rate and respiratory rate from accelerometer measurements (Healthdot) and/or the metrics calculated from the PPG and accelerometer signals collected by the Elan could have predicted a deterioration of health in surgical patients. This hypothesis will be accepted or rejected based on the outcome of this clinical investigation.

Secondary hypotheses
• The calculated heart rate and respiratory rate of the HealthDot are comparable to the gold

standard used in the at the hospital.
• The HealthDot is usable and does not interfere with the workflow of the hospital staff.
• The HealthDot is usable and does not interfere with normal daily activities of the patient in hospital and at home.
• The offline metrics using Elan collected data in the perioperative period are comparable to those obtained from gold standard patient monitoring.

Study design

First Patient First Visit 16-APR-2019 (actual)
Last Patient Last Visit 17-AUG-2020 (actual)

Contacts

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Eligibility criteria

Inclusion criteria

• Adult
• Willing and able to sign informed consent form
• Willingness to abstain from visiting a sauna during the study period
• Willingness to dry area where the HealthDot is applied in a dipping fashion after washing
• Willingness to abstain from flying during the study period of time
• Elective surgery
• General anesthesia required for surgery

Exclusion criteria

• General inmates of psychiatric wards, prisons, or other state institutions

• Investigator or any other team member involved directly or indirectly in the conduct of the clinical study
• Any skin condition, for example prior rash, discoloration, scars or open wounds at the area of investigation of both devices
• Pregnant, or breastfeeding
• Known to be allergic for the tissue adhesive used in the HealthDot.
• Use of topical that is known to influence the skin at the test area (such as medical and non-medical creams or lotions)
• Patient with active implantables such as Implantable Cardioverter Defibrilator (ICD) and pacemaker
• Unable to understand instructions
• Expected participation less than 2 weeks
• Left lower rib (place where HealthDot will be applied) is involved in the area of surgery, area of disinfection or area where bandages are needed.
• Area on arm where the Elan device is applied is involved in the surgical procedure.
• Patients with antibiotic resistant infections (e.g. MRSA).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-04-2019
Enrollment:	350
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	14-03-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7602
Other	METC MMC : w19.001

Study results