PJ-013483 FLAGSHIP Transitional Care Study 3

Published: 18-02-2019
Last updated: 12-04-2024

To evaluate the sensitivity and specificity for the prediction of deterioration after surgery using the data calculated based on accelerometer and/or PPG measurements

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON48030

Source
ToetsingOnline

Brief title
TRICA

Condition

- Other condition

Synonym
patients after surgery

Health condition

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

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Philips Electronics Nederland B.V. Research

Intervention

Keyword: Accelerometer, Connectivity, Hospital to home, Photoplethysmography

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.

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

Postoperative complications are frequently encountered at the surgical ward. Complications can lead to major adverse events such as unplanned intensive care unit (ICU) admissions, cardiorespiratory arrest or even death with a postoperative in-hospital mortality rate of 4%. They are also associated with prolonged length of stay. Timely detection of patients at risk of complications is important to initiate appropriate treatment and prevent major adverse events. Various strategies have been developed and studied to reduce the number of adverse events. Risk stratification is applied in the pre- and intra-operative setting by taking into account patient characteristics and vital signs. Studies show that of all vital signs measured heart rate and respiratory rate are the most predictive for deterioration of health. In this

study two technologies (accelerometer and photoplethysmography) will be tested to assess i.a. heart rate and respiratory rate of patients during the transition from hospital to home. Data will be analysed retrospectively after the study has been closed out and the vital signs will be compared to readmission and adverse events to see if the events could have been predicted due to the device measurements. No clinical decisions or intervention will be performed based on the measurements done during the study.

Study objective

To evaluate the sensitivity and specificity for the prediction of deterioration after surgery using the data calculated based on accelerometer and/or PPG measurements

Study design

This is a study at one site in the Netherlands. No randomization or blinding will be done. 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). Additionally, 20 patients of the 350 will be recruited to wear the HealthDot (for up to 1 week) as well as the Elan (for 48 hours) for up to 1 week before surgery to get their baseline values on heart rate and respiratory rate. 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 a MSX box to Philips.

Study burden and risks

For the patients participating in this investigation no benefits have been identified. Potential chemical, electrical, biological hazards associated with the devices as well as risks associated with the devices and their potential interference with the clinical work flow have been identified, scored and if needed mitigated (see Risk Management Plan and Risk Management Summary Matrix of PJ-013483 FLAGSHIP Transitional Care Study 3). Though the patients undergo surgery with the associated risks of this procedure this is not part of the study and the study does not influence the surgery risks. The placement of the devices will add some additional burden to the patient not related to her/his stay in hospital, however this additional burden is low and the risks are acceptable justifying the execution of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-04-2019
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO

Date:	18-02-2019
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	27-05-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	16-12-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
CCMO	NL68560.015.18