PJ-013483 FLAGSHIP Transitional Care Study 3

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27909

Bron
Nationaal Trial Register

Verkorte titel
TRICA

Aandoening

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.

Ondersteuning

Primaire sponsor: Philips Electronics Nederland B.V., acting through Research, Eindhoven, NL
Overige ondersteuning: Category 3 funding by Philips Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

• 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).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	16-04-2019
Aantal proefpersonen:	350
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	14-03-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten