Force-frequency Relationship and Post-extrasystolic Potentiation Detection

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Using Force-frequency relationship and post-extrasystolic potentiation measured by photoplethysmography at the wrist is able to accurately differentiate failing hearts from non-failing hearts

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

Samenvatting

ID

NL-OMON24835

Bron
Nationaal Trial Register

Verkorte titel
FFR-PESP

Aandoening

Heart failure

Ondersteuning

Primaire sponsor: Catharina Ziekenhuis Eindhoven, The Netherlands
Overige ondersteuning: ITEA3 (project 15032 eWatch)
High Tech Campus 69-3
5656 AG Eindhoven
The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Understanding of the level of feasibility of unobtrusive PESP and FFR measurement with green PPG measured at the wrist and its relation to PESP and FFR measurement by using ABP and ECG

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Heart failure (HF) is a clinical condition affecting 1-2% of the population in the Western world. In systolic HF, the contractile performance of the heart is reduced causing low cardiac output. This is traditionally measured by means of imaging technologies such as nuclear imaging, MRI or ultrasound and expressed as ejection fraction (EF). In clinical practice, this remains a poor parameter as symptoms and prognosis only marginally correlate with EF; moreover, it does not allow constant therapy optimization or prediction of imminent adverse events.
Systolic functioning of the myocardium can also be studied with the concepts of force-frequency relationship (FFR) and force-interval relationship of the heart. Force-frequency and force-interval relationships describe the changes in the contractile force of the heart in relation to the changes of the stimulation rate. In normal FFR, contractility increases at higher heart rates; this phenomenon is reduced or leveled off in heart failure. Post-extrasystolic potentiation (PESP) is a concept of force-interval relationship in which the contractility of the heart increases for the beat following the compensatory pause after an extrasystolic beat. Several studies have shown an enhanced PESP in the HF population when compared to patients with a non-failing heart. FFR and PESP could be used as diagnostic tools and prognostic markers in heart failure patients. The above studies have been mainly conducted by using invasive measures. Philips Research has developed wearable technology based on photoplethysmography (PPG) which is an unobtrusive measurement of blood volume changes in the tissue. The aim of this study is to explore if the PPG-waveform can be correlated with invasive arterial blood pressure (ABP) and whether it can be used for detecting PESP and FFR.
Objective: The objectives of this study are to acquire PPG data in patients during an ablation procedure simultaneously with reference measurements (ECG, ABP), investigate differences in PPG measurement between patients with failing and non-failing hearts, and to develop methods to detect PESP and FFR from PPG.
Study design: The study is an observational study.
Study population: Twenty adult patients to be treated with ablation for premature ventricular contractions and/or ventricular tachycardia: 10 patients with left ventricular ejection fraction (LVEF) < 40% and 10 patients with LVEF >= 50%.
Main study parameters/endpoints: The main study parameters are simultaneous ECG, ABP, PPG, and accelerometer recordings that can be used to study differences between patients with failing and non-failing hearts.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: In the study, ECG, ABP, PPG, and accelerometer data will be collected during a pre-defined stimulation protocol before ablation and during the cardiac ablation procedure itself. In every ablation procedure, cardiac stimulation protocols are used to induce

arrhythmias. These stimulation protocols depend on the clinical problem and the patient's condition. The study protocol is similar to the standard procedural protocols; additional stimulation manoeuvres for the study is left to the discretion of the treating physician. Wearing the Elan to collect PPG and accelerometer data during the procedures are additional to the usual/standard clinical care.
During cardiac pacing, arrhythmias can occur, as this is the purpose of the procedure. It speaks for itself that patients and personnel are aware of this, and are trained and prepared for adequate treatment. We therefore conclude that there are no additional risks associated with this study. Most of the study does not interfere with usual clinical care. The only addition will be wearing the Elan wristband and a short pacing protocol (up to 10 minutes) that is not part of usual/standard clinical care. The burden for all the patients volunteering in the study is considered minimal.

Doel van het onderzoek

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Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult
Fluent in Dutch
Able and willing to provide informed consent
Scheduled to undergo PVC or VT ablation, thaught to originate from the LV

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

HFpEF NYHA III-IV
Presence of wounds, injuries or infectious diseases on the skin where the wrist-wearable device will be placed

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 gestart
(Verwachte) startdatum:	02-03-2020
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	25-02-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55539
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8412
CCMO	NL64620.100.18
OMON	NL-OMON55539

Resultaten