Force-frequency Relationship and Post-extrasystolic Potentiation Detection

No registrations found.

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

Summary

ID

NL-OMON24835

Source
Nationaal Trial Register

Brief title
FFR-PESP

Health condition

Heart failure

Sponsors and support

Primary sponsor: Catharina Ziekenhuis Eindhoven, The Netherlands
Source(s) of monetary or material Support: ITEA3 (project 15032 eWatch)
High Tech Campus 69-3
5656 AG Eindhoven
The Netherlands

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

N/A

Study description

Background summary

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.

Study objective

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

Study design

N/A

Intervention

N/A

Contacts

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Scientific
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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

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:	Recruiting
Start date (anticipated):	02-03-2020
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-02-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55539
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results