PREDICT-MVO.

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We hypothesize that a combined intracoronary pressure-flow measurement directly after percutaneous coronary intervention is a measure for predicting the occurrence of microvascular obstruction in the days following the acute event.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24593

Bron
NTR

Verkorte titel
PREDICT-MVO

Aandoening

atherosclerosis
acute myocardial infarction
microvascular obstruction

Ondersteuning

Primaire sponsor: Volcano Precision Guided Therapy
Excelsiorlaan 41
B - 1930 Zaventem
Belgium
Phone: + 32 2 679 10 76
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Overige ondersteuning: investigator initiated

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. MVRI;
2. PET;
3. MRI.

Toelichting onderzoek

Achtergrond van het onderzoek

Patients with acute STEMI that are Presented at catheterization laboratory within 6 hours after onset of symptoms. Directly following successful revascularization and stent-placement, using a combowire intracoronary resistance measurements will be done distal to the coronary stent. Using the ComboMap Pressure and Flow System simultaneous pressure and Doppler flow velocity will be recorded. A second resistance measurement will be done in a controlateral artery without a stenosis to serve as a reference value. At day 4 and day 90 after the acute event, a cardiac perfusion PET scan will be performed. Standard care includes angiographic measurements as well as electrocardiography, Cardioac magnetic resonance (CMR) examination and also blood samples will be taken.

Main study parameters/endpoints:

The main study endpoints are the resistance values as measured with the combowire and the total infarct size and MVO as measured by CMR.
Secondary endpoints are all other parameters measured as well as adverse events.

Doel van het onderzoek

We hypothesize that a combined intracoronary pressure-flow measurement directly after percutaneous coronary intervention is a measure for predicting the occurrence of microvascular obstruction in the days following the acute event.

Onderzoeksopzet

T=0, T=1, T=4, T=7, T=90.

Onderzoeksproduct en/of interventie

Intracoronary pressure-flow measurements (MVRI).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with STEMI;

2. Presenting at cath lab < 6 hours after onset of symptoms.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous MI in same artery;

2. Significant three-vessel disease (lesions >70%);

3. CABG;

4. Unsuccessful primary PCI (TIMI 0-1);

5. Cardiogenic shock;

6. Extreme fear and severe chest pain;

7. Poor kidney function (eGFR < 30 mg/ml/min);

8. Refusal or inability to give informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	21-11-2011
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-11-2011
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	NL3016
NTR-old	NTR3164
Ander register	METC VUmc : 2011/197
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A