Veiligheid en effectiviteit van PCI optimalisatie door het gebruik van hoge resolutie IVUS vergeleken met de standaard behandeling bij patiënten met een lage FFR na de procedure

Gepubliceerd: 19-09-2017 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON25972

Bron
NTR

Aandoening

FFR, post PCI FFR, IVUS, PCI, atherosclerosis, atherosclerose, dotter, post procedurele FFR

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: ACIST Medical Systems, Inc. Corporate Headquarters

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Target vessel failure, defined as composite of cardiac death, target vessel Q-wave or non-Q wave myocardial infarction, coronary artery bypass graft and clinically driven target vessel

revascularization.

Toelichting onderzoek

Achtergrond van het onderzoek

Fractional flow reserve (FFR) after a percutaneous coronary intervention (PCI) proved to be a strong and independent predictor of Major Adverse Cardiac Events (MACE). A number of factors can cause a post PCI pressure drop over a treated segment which can be revealed by intravascular ultrasound (IVUS). It is currently unknown if optimization of impaired post PCI FFR with IVUS might improve patient outcome.

The objective of the FFR-REACT trial is to assess if FFR guided PCI optimization directed by High Definition (HD)-IVUS in patients with a post-PCI FFR below 0.90 will improve target vessel failure. In this prospective trial 290 patients with a post PCI FFR <0.90 will be randomized (1:1) to either standard of care (no additional intervention) or IVUS-directed optimization to a FFR ≥ 0.90 (treatment arm). Assuming that 45% of patients will have a post PCI FFR <0.90, approximately 640 patients undergoing PCI will need to be enrolled. Post PCI FFR measurements will be performed in all patients. The total follow-up period for all patients will be 3 years.

The primary study end point is defined as target vessel failure, a composite of cardiac death, target-vessel myocardial infarction and clinically driven TVR at 1 year.

This study will provide novel insights for a potentially new patient group where post PCI FFR is followed by IVUS to optimize therapy.

Onderzoeksopzet

Patients will be followed-up at 6 months, 1, 2 and 3 years post PCI

Onderzoeksproduct en/of interventie

FFR-guided optimization directed by the ACIST HDi® IVUS System using the Kodama® IVUS catheter will be performed in the treatment arm. Patients will be followed for up to 3 years.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age ≥18

2. Stable- or unstable angina or Non-ST segment elevation myocardial infarction

3. Target lesion stenosis ≥ 50% by visual estimation or QCA successfully treated by PCI and stenting

4. Written informed consent;

5. The patient agrees to the follow

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with ST-elevation myocardial infarction (STEMI) or evidence of myocardial infarction within 72 hours before the index procedure

2. Target vessel distal reference diameter <2.25mm

3. Cardiogenic shock or severe hemodynamic instability

4. Unsuccessful stenting

5. PCI without stenting

6. Inability to perform post procedure FFR

7. The patient has other medical illnesses (i.e., cancer) that may cause the patient to be non-compliant with the protocol, confound the data interpretation or is associated with limited life expectancy (i.e., less than one year).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2017
Aantal proefpersonen:	640
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-09-2017
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	NL6523
NTR-old	NTR6711
Ander register	METC-Rotterdam : MEC-2017-489

Resultaten