Biomarker and Imaging Study to assess the ability of high doses rosuvastatin to decrease artherosclerosis in coronary arteries.

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A high dose of rosuvastatin significantly decreases or halt the progress of the necrotic core volume present in a non-intervened coronary segment as assessed by IVUS-VH.

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

Samenvatting

ID

NL-OMON24500

Bron
NTR

Verkorte titel
IBIS-3

Aandoening

Coronary artery disease

Ondersteuning

Primaire sponsor: Erasmus Medical center (Thoraxcenter)
Overige ondersteuning: Astra Zeneca

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of this clinical trial is to determine whether 40 mg rosuvastatin during 12 months decreases necrotic core as assessed by IVUS - VH at 52 weeks.

Toelichting onderzoek

Achtergrond van het onderzoek

More than half of all acute coronary syndromes (ACS) are caused by a rupture of vulnerable atherosclerotic plaque, which is characterized by the presence of a thin inflamed fibrous cap and a large necrotic core pool. Intravascular ultrasound-virtual histology (IVUS-VH) allows tissue characterization of four different plaque compositions, such as fibrous, fibro-fatty, dense calcified and necrotic core. Although a high dosage statin reduces coronary plaque size and necrotic core in carotid arteries, it remains unknown whether there is a similar effect on the necrotic core present in coronary atherosclerotic plaque. The IBIS-3 study is a single-center, non-randomized study designed to evaluate the ability of a high dose rosuvastatin in reducing the necrotic core of a non-intervened coronary segment assessed in vivo with IVUS-VH within 12-months (primary endpoint).

Doel van het onderzoek

A high dose of rosuvastatin significantly decreases or halt the progress of the necrotic core volume present in a non-intervened coronary segment as assessed by IVUS-VH.

Onderzoeksopzet

Baseline procedure, followed by follow-up at 2, 6 and 12 months. Angiographic follow-up, including IVUS-Virtual Histology (VH) and LipiScan assessments at 12 month.

Onderzoeksproduct en/of interventie

1. Off-line IVUS-VH of one ‘study vessel’ at baseline and 52 weeks follow-up;

2. LipiScan examination of the ‘study-vessel’ at baseline and 52 weeks follow-up;

3. Blood samples for lipid profile at baseline and 52 weeks follow-up (hs-CRP, genetic, SNP, RNA, proteomic and lipidomic analysis as well as cellular and functional analysis will be obtained);

4. Rosuvastatin 40 mg (uptitrated within 30 days) for 12 months.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. More than 18 years old;

2. Written informed consent;

3. Patients with stable angina pectoris or unstable angina pectoris (Braunwald Class I-III, B-C) or patients with documented silent ischemia or patients with an acute myocardial infarction;

4. Patients eligible for coronary revascularisation in the native coronary artery/arteries or candidate for invasive coronary diagnostic procedure;

5. Willing to follow all study procedures including adherence to lipid-lowering diet, study visits and compliance with study treatment regimen.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Braunwald class IA, IIA, IIIA (unstable angina caused by non-cardiac illness);

2. Women who are pregnant or women of childbearing potential who do not use adequate contraception;

3. Known allergies to aspirin, clopidogrel bisulfate (Plavix ®), Ticlopdine (Ticlid ®) heparin, stainless steel, copper or a sensitivity to contrast media which cannot be adequately pre-medicated;

4. Previous participation in this study;

5. Life expectancy of less than one year or factors making clinical and/or angiographic follow-up difficult;

6. Planned coronary bypass surgery;

7. Planned major non-cardiac surgery;

8. The subject has a history of bleeding diathesis or coagulopathy;

9. The subject suffered disabling stroke within the past year;

10. Known major hematologic, neoplastic, metabolic, gastrointestinal or endocrine dysfunction which, in the judgment of the Investigator, may affect the patient’s ability to complete the study;

11. History of malignancy, except in patients who have been disease-free >5 years or whose only malignancy has been basal or squamous cell skin carcinoma.

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:	04-02-2010
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-04-2011
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	NL2734
NTR-old	NTR2872
Ander register	MEC Erasmus MC : 2009-237
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A