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

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON24500

**Source**
NTR

**Brief title**
IBIS-3

**Health condition**

Coronary artery disease

### Sponsors and support

**Primary sponsor:** Erasmus Medical center (Thoraxcenter)
**Source(s) of monetary or material Support:** Astra Zeneca

### Intervention

### Outcome measures

**Primary outcome**

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.

### Secondary outcome

To determine whether rosuvastatin reduces lipid core as assessed by LipiScan at 52 weeks.

## Study description

### Background summary

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).

### Study objective

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.

### Study design

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.

### Intervention

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.

# Contacts

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# Eligibility criteria

## Inclusion criteria

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.

## Exclusion criteria

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.

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 04-02-2010 |
| Enrollment: | 300 |
| Type: | Anticipated |

# Ethics review

Positive opinion

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|---|---|
| Date: | 27-04-2011 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL2734 |
| NTR-old | NTR2872 |
| Other | MEC Erasmus MC : 2009-237 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A