# Multicenter trial of elective revascularization in patients with diabetes mellitus and mild anginal complaints

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
20/12/2005		☐ Protocol		
Registration date 20/12/2005	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 24/08/2009	Condition category Nutritional, Metabolic, Endocrine	[] Individual participant data		

## Plain English summary of protocol

Not provided at time of registration

# Contact information

#### Type(s)

Scientific

#### Contact name

Dr J.J. Wiersma

#### Contact details

Academic Medical Centre, Department of Cardiology, B2-124, Meibergdreef 9 Amsterdam Netherlands 1105 AZ +31 (0)20 5662749 j.j.wiersma@amc.uva.nl

# Additional identifiers

Protocol serial number NTR173

# Study information

#### Scientific Title

#### Acronym

**MERIDIAN** 

#### **Study objectives**

To determine whether a strategy of invasive treatment (relative to continued medical treatment) of patients with type 2 diabetes mellitus, mild symptoms of stable angina pectoris, and documented myocardial ischemia lead to a decrease in cardiac complications

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Received from local medical ethics committee

#### Study design

Multicentre randomised open label active controlled parallel group trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Diabetes Mellitus type II (DM type II), Coronary artery disease

#### **Interventions**

Patients that qualify for admission in the randomised trial are randomly assigned to one of the following treatment strategies:

- 1. Invasive treatment
- 2. Continued medical treatment

#### Invasive treatment:

Patients undergo coronary angiography as soon as possible after randomisation. Angiography can be performed at either the referring center or the intervention center. Coronary angiography is performed according to current practice guidelines by experienced operators. The sheath and catheter size should not exceed 6 F.

All patients follow the routine assessment in the regular heart team conferences, in which the referring cardiologist, the heart surgeon, and the intervention cardiologist take decisions about the type of revascularisation. The Dutch Guidelines for revascularisation are followed except for the required intensity of the anginal complaints.

PTCA procedures are performed under routine protocols of the participating catheterisation laboratories. The aim is to treat all culprit lesions i.e. those lesions that are associated with significant deficits on the myocardial perfusion scintigram. All lesions are preferably treated with a paclitaxel-coated stent, unless contra-indicated or not available. Blood samples for the measurement of concentrations of CK and CK-MB are taken at 6, 12, 18, and 24 hours after the end of a percutaneous procedure. These concentrations are measured at the local laboratories. Treatment with GP IIb/IIIa receptor inhibitors is recommended. Clopidogrel is started before the

PTCA and continued until at least 1 month after stenting and until 6 months after stenting when a drug-eluting stent is placed.

Bypass surgery is performed under the routine protocols of the participating hospitals. The aim is to achieve complete revascularisation.

After a revascularisation procedure, the antianginal medication is reduced as much as possible.

#### Continued medical treatment:

Anti-anginal medication: Beta-blockers, calcium antagonists, oral nitrates may be given as clinically needed.

Acetyl salicylic acid: Acetyl salicylic acid at a dose of at least 75 mg/24 hours is given to all patients at least until the end of follow-up (unless contraindicated).

Clopidogrel: Clopidogrel is given to patients that undergo a percutaneous intervention in combination with stent placement. Clopidogrel is given at a starting dose of 300 mg immediately before stent placement, followed by 75 mg daily for 3 months. Moreover, clopidogrel at a dose of 75 mg/24 hours may also be given to patients with a contra-indication for acetyl salicylic acid. Statins: Aggressive lipid lowering therapy should be started in all patients as soon as possible after informed consent has been obtained. Further treatment of dislipidemia is according to present consensus guidelines.

ACE-inhibitors: ACE-inhibitors: Treatment with ramipril is started as soon as possible after informed consent has been obtained. Ramipril is started at a dose of 2.5 mg/24 hours for one week, followed 5.0 mg/24 hours for three weeks. After one month, the treatment is continued at a dose of 10 mg/24 hours.

If deemed necessary by the treating physician, another ACE inhibitor or an AT-II receptor antagonist may be given.

Other antihypertensive drugs: Hypertension is treated according to the current guidelines, which aim at a systolic blood pressure of <140 mmHg and a diastolic blood pressure of <85 mmHg.

Other drugs: Other drugs be given when indicated; their use is recorded.

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome(s)

One or more of the following complications within the duration of follow-up:

- 1. All-cause mortality
- 2. Non-fatal myocardial infarction
- 3. Hospital admission for acute coronary syndrome

#### Key secondary outcome(s))

Each of the above components of the composite endpoint:

- 1. Cardiac mortality
- 2. Newly developed diabetic morbidity (diabetic retinopathy, diabetic nephropathy, and changes in blood glucose regulation) documented in routine clinical practice
- 3. Functional status at one and two years
- 4. Quality of life

#### Completion date

02/07/2004

# Eligibility

#### Key inclusion criteria

- 1. A history of diabetes mellitus type 2, evidenced by either of the following
- 1.1 Treatment with oral antidiabetic medication
- 1.2 Treatment with insulin after a period of treatment with oral antidiabetic medication
- 1.3 Treatment with insulin, started after the 50th year
- 1.4 A fasting plasma glucose concentration of at least 7.0 mmol/l or a non-fasting glucose concentration of at least 11.0 mmol/l, in two samples taken on separate days
- 2. Stable mild complaints of angina pectoris (Canadian Cardiovascular Society class I or II, on medical treatment)

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### Key exclusion criteria

- 1. Younger than 30 years of age
- 2. Previous myocardial infarction and/or acute coronary syndrome in the previous two months
- 3. Unstable angina (any category in Braunwald's classification) in the previous two months
- 4. Previous percutaneous intervention in the previous six months
- 5. Serious complaints of effort angina pectoris (CCS class III or IV)
- 6. Known coronary anatomy unsuited for coronary revascularization
- 7. An ejection fraction of less than 35%, measured by any technique
- 8. Contra-indication for bypass surgery (i.e. co-morbidity)
- 9. History of a hemorrhagic stroke at any time, or stroke or transient ischemic accident (TIA) of any etiology within 30 days of randomization
- 10. History of a bleeding diathesis, or evidence of active abnormal bleeding within 30 days of randomization
- 11. Known platelet count of <100,000/mm3
- 12. Severe hypertension (systolic blood pressure >180 mmHg or diastolic blood pressure over 100 mmHg, after treatment)
- 13. Major surgery within 6 weeks prior to randomization
- 14. Congenital heart disease
- 15. Apparent cardiomyopathy
- 16. Severe valvular heart disease
- 17. Serious bronchial asthma
- 18. Malignancies or other diseases with a limited life expectancy
- 19. Serious kidney failure (plasma creatinin level >250 µmol/l)
- 20. Body-weight >120 kg
- 21. Co-existent condition associated with a limited life expectancy
- 22. Previous participation in this study or any other trial within the previous 30 days

- 23. Circumstances that prevent follow-up (no permanent home or address, transient etc.)
- 24. Pregnant women or women of child bearing potential who do not use adequate contraception
- 25. Familial hypercholesterolemia or an LDL cholesterol concentration over 55 mmol/l (after treatment)

# Date of first enrolment 01/10/2002

Date of final enrolment 02/07/2004

# **Locations**

# **Countries of recruitment**Netherlands

Study participating centre Academic Medical Centre, Amsterdam Netherlands 1105 AZ

# Sponsor information

#### Organisation

Academic Medical Centre (AMC) (Netherlands)

#### **ROR**

https://ror.org/03t4gr691

# Funder(s)

#### Funder type

Research organisation

#### **Funder Name**

Netherlands Organisation for Health Research and Development (ZonMw)

#### Alternative Name(s)

Netherlands Organisation for Health Research and Development

#### **Funding Body Type**

Private sector organisation

## **Funding Body Subtype**

Other non-profit organizations

#### Location

Netherlands

#### **Funder Name**

Dutch Heart Foundation (Netherlands)

## Alternative Name(s)

**Heart Foundation** 

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

#### Location

Netherlands

# **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2009		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes