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

Submission date	Recruitment status
20/12/2005	No longer recruiting
Registration date	**Overall study status**
20/12/2005	Completed
Last Edited	**Condition category**
24/08/2009	Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.amc.uva.nl/meridian

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/10/2002

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

Age group
Adult

Sex
Both

Target number of participants
800

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)

Sponsor details
Meibergdreef 9
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Sponsor type
University/education

Website
http://www.amc.uva.nl/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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