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

Gepubliceerd: 31-08-2005 Laatst bijgewerkt: 13-12-2022

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...

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

Samenvatting

ID

NL-OMON20816

Bron
NTR

Verkorte titel
MERIDIAN

Aandoening

Stable and mild complaints of coronary artery disease in patients with diabetes mellitus type 2.

Ondersteuning

Primaire sponsor: * The Netherlands Heart Foundation (NHS)
* The Netherlands Organisation for Health Research and Development (ZonMw)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

One or more of the following complications within the duration of follow-up:
a. All-cause mortality;
b. Non-fatal myocardial infarction;
c. Hospital admission for acute coronary syndrome.

Toelichting onderzoek

Achtergrond van het onderzoek

Study design:

Consenting patients in 26 hospitals with type 2 diabetes mellitus and mild complaints of angina pectoris (Canadian Cardiovascular Society Class I or II) are screened for deficiency of oxygen supply to the heart by nuclear heart scan (myocardial perfusion scintigraphy) and/or exercise stress testing.

Patients with positive myocardial perfusion scintigraphy and/or exercise stress test are randomly assigned to invasive treatment or to continued medical treatment.

Invasive treatment includes, in addition, immediate angiography followed by revascularization, if appropriate. The Dutch guidelines for revascularization are followed. Continued medical treatment includes optimization of the anti-anginal medication, of the lipid lowering medication and the glucose regulation.

All patients visit the outpatient clinic at two and six months and at six-month intervals until the end of the study. The remaining patients without reversible oxygen deficit are contacted a year after randomization.

The Meridian trial was prematurely discontinued on August 02, 2004 by the financial sponsor The Netherlands Organisation for Health Research and Development (ZonMw), due to slow inclusion rates. At that moment, a total of 336 patients were screened of which 156 were eligible for participation in the randomized trial.

Doel van het onderzoek

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?

Onderzoeksproduct en/of interventie

Patients that qualify for admission in the randomized 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 randomization. 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 revascularization. The Dutch Guidelines for revascularization are followed except for the required intensity of the anginal complaints.

PTCA procedures are performed under routine protocols of the participating catheterization 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 revascularization.

After a revascularization 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/24h 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/24h 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 h for one week, followed 5.0 mg/24 h for three weeks. After one month, the treatment is continued at a dose of 10 mg/ 24 h.

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.

Contactpersonen

Publiek

Academic Medical Center (AMC),
Department of Cardiology, B2-124,
P.O. Box 22660
J.J. Wiersma
Meibergdreef 9

Amsterdam 1100 DD
The Netherlands
+31 (0)20 5662749

Wetenschappelijk

Academic Medical Center (AMC),
Department of Cardiology, B2-124,
P.O. Box 22660
J.J. Wiersma

Meibergdreef 9

Amsterdam 1100 DD
The Netherlands
+31 (0)20 5662749

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. A history of diabetes mellitus type 2, evidenced by either of the following:

a. Treatment with oral antidiabetic medication;

b. Treatment with insulin after a period of treatment with oral antidiabetic medication;

c. Treatment with insulin, started after the 50th year;

d. 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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 5.5 mmol/l (after treatment.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-10-2002
Aantal proefpersonen:	800
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	31-08-2005
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	NL138
NTR-old	NTR173

Register	ID
Ander register	: N/A
ISRCTN	ISRCTN65663256

Resultaten

Samenvatting resultaten

N/A