A double blind placebo controlled study on the effect of cerivastatin on the process of atherosclerosis in non-insulin dependent diabetes mellitus.

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N/A

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

Samenvatting

ID

NL-OMON20255

Bron
Nationaal Trial Register

Verkorte titel
CERDIA study

Aandoening

Non-insulin dependent diabetes mellitus (NIDDM)

Ondersteuning

Primaire sponsor: Leiden University Medical Center, Dept. of General Internal Medicine and dept. of Cardiology.
Overige ondersteuning: Bayer, Nl

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The change of IMT and distensibility after 24 months using B-mode ultrasound at the carotid artery level.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective:

Cardiovascular disease (CVD) is the most important cause of mortality in patients with type 2 diabetes.

We aimed to determine the effect of statin therapy versus placebo on the progression of carotid intima-media thickness (IMT) in type 2 diabetic patients without manifest CVD.

Research design and methods:

A randomized, placebo-controlled, double-blind clinical trial was performed in 250 patients with type 2 diabetes.

Patients were given either 0.4 mg cerivastatin or placebo daily. In August 2001, when cerivastatin was withdrawn from the market, 0.4 mg cerivastatin was replaced by 20 mg simvastatin without deblinding the study.

The primary end point:

The change of mean common carotid IMT, as measured by B-mode ultrasound, over 2 years.

Doel van het onderzoek

N/A

Onderzoeksproduct en/of interventie

1. Patients of the intervention group will be treated with cerivastatin 0.4mg/day for two years;

2. Controls will get placebo. In August 2001, when cerivastatin was withdrawn from the

market, 0.4 mg cerivastatin was replaced by 20 mg simvastatin without deblinding the study.

Contactpersonen

Publiek

Leiden University Medical Center (LUMC)
Department of Thrombosis and Haemostasis
Room C4-68
P.O Box 9600

M.V. Huisman
Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71 5262085

Wetenschappelijk

Leiden University Medical Center (LUMC)
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patient with Non-Insulin Dependent Diabetes Mellitus. The diagnosis based upon the age of onset, the presence of obesity and the absence of ketoacidosis at the time of diagnosis and the use of diet or oral anti-diabetic drugs for more than one year from diagnosis;

2. Males and females;

3. Age range: 30 - 80 years;

4. Given written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Angina pectoris;

2. History of myocardial infarction, PTCA or CABG;

3. Positive ECG criteria for a myocardial infarction in the past;

4. History of ischemic CVA;

5. Peripheral artery by-pass surgery or amputation because of atherosclerotic disease or claudication;

6. Secondary diabetes (steroid induced, Cushing, haemochromatosis, alcohol abuse, pancreatitis);

7. Untreated or uncontrolled hyperthyroidism or hypothyroidism;

8. Active liver disease (hepatitis, cirrhosis or biliary obstruction) or hepatic dysfunction (repeated aminotransferase-values more than 150% of the upper limit of normal (ULN);

9. Impaired renal function with creatinine clearance < 30 ml/min;

10. Baseline CK values $ 3 x ULN;

11. Fasting total cholesterol above 6.9 mmol/l despite diet or below 4.0 mmol/l or triglycerides above 6.0 mmol/l;

12. Any hereditary dyslipidemia;

13. Known allergy to HMG-coA-reductase inhibitors;

14. Pregnancy or lactation;

15. Women of childbearing potential, not using adequate contraceptives;

16. Use of lipid lowering medication, within eight weeks before the start of the study;

17. Life expectancy of less than two years;

18. Any other condition that in the opinion of the investigator could lead to inappropriate absorption, metabolism or elimination of the medication or compromise the patients= safety, or lead to insufficient compliance with the study drug regimen.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-08-1999
Aantal proefpersonen:	250
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-09-2005
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	NL250
NTR-old	NTR288
Ander register	: N/A
ISRCTN	ISRCTN51822988

Resultaten

Samenvatting resultaten
-Beishuizen ED, van de Ree MA, Jukema JW, Tamsma JT, van der Vijver JC, Meinders AE, Putter H, Huisman MV. Diabetes Care 2004;27:2887-92.
-Beishuizen ED, Tamsma JT, Jukema JW, van de Ree MA, van der Vijver JC, Meinders AE, Huisman MV. Diabetes Care 2005;28:1668-74.
-Beishuizen ED, Jukema JW, Tamsma JT, van de Ree MA, van der Vijver JC, Putter H, Maan AC, Meinders AE, Huisman MV. Diabetes Care 2005;28:1675-9.