

A double blind placebo controlled study on the effect of cerivastatin on the process of atherosclerosis in non-insulin dependent diabetes mellitus (type 2).

Gepubliceerd: 29-01-2007 Laatste bijgewerkt: 13-12-2022

To assess the effect of statin therapy on the process of atherosclerosis in type 2 diabetes without manifest cardiovascular disease.

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

Samenvatting

ID

NL-OMON21494

Bron

NTR

Verkorte titel

N/A

Aandoening

Patients with type 2 diabetes without manifest cardiovascular disease.

Ondersteuning

Primaire sponsor: The trial was investigator driven (see scientific contact).

The trial was supported by Bayer BV(Mijdrecht, the Netherlands). After the withdrawal of cerivastatin from the market, Merck, Sharp and Dome (Haarlem, the Netherlands) supplied the simvastatin/placebo tablets for the remaining study period.

Overige ondersteuning: See sponsor(s).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change from baseline in mean intima-media thickness (IMT) of the common carotid artery.

Toelichting onderzoek

Achtergrond van het onderzoek

The goal of the trial was to study the effect of statin therapy on vascular parameters for atherosclerosis in type 2 diabetes without manifest cardiovascular disease.

250 patients received statin therapy (cerivastatin 0.4 mg, later simvastatin 20 mg) or placebo for 2 years in this double blind placebo controlled trial. Endpoints were IMT, FMD, distensibility, 48 hour AECG and laboratory parameters.

Doel van het onderzoek

To assess the effect of statin therapy on the process of atherosclerosis in type 2 diabetes without manifest cardiovascular disease.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Cerivastatin 0.4 mg (Bayer BV, Mijdrecht, the Netherlands) daily or placebo for 2 years.

After the withdrawal of cerivastatin from the market, 0.4 mg cerivastatin was replaced by 20 mg simvastatin (Merck, Sharp and Dome, Haarlem, the Netherlands), without deblinding the study.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with type 2 diabetes for at least 1 year;
2. Age 30-80 years;
3. Written informed consent;
4. With no prior cardiovascular disease;
5. Total cholesterol 4.0-6.9 mmol/l
triglycerides < 6.0 mmol/l.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Prior cardiovascular disease;
2. current/recent use of lipid lowering drugs;
3. Impaired renal function (<30 ml/min);
4. CK values > 3 ULN;
5. Uncontrolled thyroid disease;

6. Liver disease or ALAT > 2 ULN;
7. Inadequate contraception, pregnancy or lactation;
8. Life expectancy <2 years.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	25-08-1999
Aantal proefpersonen:	250
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	29-01-2007
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	NL868
NTR-old	NTR882
Ander register	: NTR288, ISRCTN51822988
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

1. Beishuizen et al: Two-year statin therapy does not alter the progression of Intima-media thickness in patients with type 2 diabetes without manifest cardiovascular disease. Diabetes Care 27:2887-2892, 2004;

2. Beishuizen et al: The effect of statin therapy on endothelial function in type 2 diabetes without manifest cardiovascular disease. Diabetes Care 28:1668-1674, 2005;

3. Beishuizen et al: No effect of statin therapy on silent myocardial ischemia in patients with type 2 diabetes without manifest cardiovascular disease. Diabetes Care 28: 1675-1679, 2005;

4. Ray et al: Vascular phenotype and subclinical inflammation in diabetic Asian Indians without overt cardiovascular disease Diab. Res. Clin. Pract. (2006), doi:10.1016/j.diabres.2006.09.021.