

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

No registrations found.

| | |
|------------------------------|---------------------|
| Ethical review | Positive opinion |
| Status | Recruitment stopped |
| Health condition type | - |
| Study type | Interventional |

Summary

ID

NL-OMON21494

Source

Nationaal Trial Register

Brief title

N/A

Health condition

Patients with type 2 diabetes without manifest cardiovascular disease.

Sponsors and support

Primary 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.

Source(s) of monetary or material Support: See sponsor(s).

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Changes in:

1. Mean IMT of the carotid bifurcation, internal carotid artery, common femoral artery and superficial femoral artery;
2. Distensibility of the common carotid artery;
3. Flow mediated vasodilation (FMD) of the brachial artery as a parameter for endothelial function;
4. 48 ambulatory ECG as a parameter for silent myocardial ischemia;
5. -hs-CRP and other blood parameters for vascular inflammation, hemostasis, fibrinolysis, platelet activation, endothelial function.

Study description

Background summary

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.

Study objective

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

Study design

N/A

Intervention

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 debinding the study.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

| | |
|---------------------|-------------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |

Recruitment

| | |
|---------------------------|---------------------|
| NL | |
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 25-08-1999 |
| Enrollment: | 250 |
| Type: | Actual |

Ethics review

| | |
|------------------|------------|
| Positive opinion | |
| Date: | 29-01-2007 |

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

| Register | ID |
|----------|------------------------------------|
| NTR-new | NL868 |
| NTR-old | NTR882 |
| Other | : NTR288, ISRCTN51822988 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

Study results

Summary results

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.