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

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
09/11/2022

Condition category
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

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
n/a

Study information

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

Acronym
CERDIA

Study objectives
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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomized placebo-controlled double-blind clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes mellitus type II (DM type II)

Interventions
1. Patients of the intervention group will be treated with cerivastatin 0.4 mg/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In August 2001, when cerivastatin was withdrawn from the market, 0.4 mg cerivastatin was replaced by 20 mg simvastatin without deblinding the study.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cerivastatin

Primary outcome(s)

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

Key secondary outcome(s))
1. The change in the prevalence of (silent) myocardial ischaemia after 24 months as monitored with 48 hour ambulatory ECG
2. The change of endothelium function after 24 months using flow mediated vasodilatation assessed by ultrasound of the a. brachialis
3. The change in blood levels of parameters for endothelial function, haemostasis, fibrinolysis, platelet activation, endothelial cell injury and vascular wall inflammation.
4. Biochemical endpoints: total cholesterol, High Density Lipoprotein (HDL)-cholesterol, (calculated) Low Density Lipoprotein (LDL)-cholesterol, triglycerides, LDL/ApoB100 ratio, Lipoprotein A-I (LpA-I), Lp(a)
5. Diabetic nephropathy: creatinine clearance and microalbuminuria
6. Clinical endpoints of cardiovascular disease

Completion date
31/03/2003

Eligibility

Key inclusion criteria
1. Patient with Non-Insulin Dependent Diabetes Mellitus. The diagnosis is based upon:
1.1. The age of onset
1.2. The presence of obesity
1.3. The absence of ketoacidosis at the time of diagnosis
1.4. 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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
250

Key exclusion criteria
1. Angina pectoris
2. History of myocardial infarction, Percutaneous Transluminal Coronary Angioplasty (PTCA) or

Coronary Artery Bypass Graft (CABG)
3. Positive Electrocardiogram (ECG) criteria for a myocardial infarction in the past
4. History of ischemic Cerebrovascular Accident (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 less than 30 ml/min
10. Baseline Creatine Kinase (CK) values more than 3 x ULN
11. Fasting total cholesterol above 69 mmol/l despite diet or below 40 mmol/l or triglycerides above 60 mmol/l
12. Any hereditary dyslipidemia
13. Known allergy to 3-Hydroxy-3-Methyl-Glutaryl (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

Date of first enrolment
01/08/1999

Date of final enrolment
31/03/2003

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (Netherlands)

ROR

https://ror.org/027bh9e22

Funder(s)

Funder type
Industry

Funder Name
Bayer B.V. (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		01/12/2004		Yes	No
Results article		01/07/2005		Yes	No
Results article		01/07/2005		Yes	No