The DALI study: a double-blind randomized placebo-controlled trial in patients with diabetes mellitus type 2 and hypertriglyceridemia.

No registrations found.

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

Summary

ID

NL-OMON24407

Source
NTR

Brief title
DALI study

Health condition

Diabetes mellitus type 2.

Sponsors and support

Primary sponsor: Erasmus Medical Center Rotterdam, Department of Internal Medicine and Departments of Biochemistry and Clinical Chemistry; Gaubius Laboratory TNO-PG, Leiden; Leiden University Medical Center; University Medical Center Utrecht, Julius Center for General Practice and Patient Oriented Research; University Medical Center Utrecht, Division of Internal Medicine
Source(s) of monetary or material Support: Parke Davis, Rotterdam, The Netherlands

Intervention

Outcome measures

Primary outcome

The effect of atorvastatin 10mg and 80mg on the reduction of triglyceride levels in patients with diabetes mellitus type 2 and hypertriglyceridemia.

Secondary outcome

The effects on other aspects of diabetic dyslipidemia.

Study description

Background summary

Objective:

In patients with diabetes mellitus type 2 intensive glucose regulation, while effective for microangiopathy, has only limited effects on the occurrence of cardiovascular disease. Diabetic patients show a characteristic dyslipidemia (high triglycerides, low HDL-cholesterol). Aggressive lowering of triglycerides might be an effective method to reduce the cardiovascular risk in these patients;

Research design and methods:

A double-blind placebo-controlled randomized study to assess the effect of 30 weeks atorvastatin 10mg and 80mg on plasma triglyceride levels in 217 patients with diabetes mellitus type 2 and fasting triglycerides between 1.5 and 6.0 mmol/L.

Study objective

Higher doses of statins will result in additional improvement of the diabetic lipid profile.

Study design

N/A

Intervention

Patients who met the in- and exclusion criteria started with a placebo run-in period. If the

lipid levels were still within the inclusion range after two weeks, patients were randomized to treatment with atorvastatin 10mg, 80mg, or placebo, administered once daily in the morning. Patients randomized to atorvastatin 80mg started with 40mg for four weeks after which the dose was increased to 80mg. The total treatment period was 30 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

1. Diabetes mellitus type 2, > 1 year;

2. Male or female;

3. HbA1c 10% or lower;

4. Fasting total cholesterol level between 4.0 and 8.0 mmol/L;

5. Fasting triglycerides level between 1.5 and 6.0 mmol/L.

Exclusion criteria

1. History of myocardial infarction, PTCA, CABG, clinical symptoms of manifest coronary artery disease (> grade II of the Canadian Cardiovascular Society), severe or unstable angina pectoris (> grade II), clinically manifest heart failure (> grade II NYHA) and severe cardiac arrhytmias;

2. Premenopausal women, patients with acute liver disease or hepatic dysfunction, impaired renal function (plasma creatinine > 150 mmol/l), a history of partial ileal bypass surgery, any surgical procedure or any systemic inflammatory disease within the last three months before randomization, malignancies, vasculitis, rheumatic arthritis, idiopathic lung fibrosis, ulcerative colitis or Crohn’s disease;

3. Patients who consumed more than 4 alcoholic drinks per day or who used systemic steroids, androgens, cyclosporin, other immunosuppressive drugs, erythromycin or mibefradil.

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):	17-06-1998
Enrollment:	217
Type:	Actual

Ethics review

Positive opinion

Date:	12-09-2005
Application type:	First submission

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	NL266
NTR-old	NTR304
Other	: N/A
ISRCTN	ISRCTN72259862

Study results

Summary results

1. Van de Ree MA, Huisman MV, Princen HM, Meinders AE, Kluft C; DALI-Study Group. Atherosclerosis 2003;166:129-35;
2. Van Venrooij FV, van de Ree MA, Bots ML, Stolk RP, Huisman MV, Banga JD; DALI Study Group. Diabetes Care Jul;25:1211-6;
3. Diabetes Atorvastin Lipid Intervention (DALI) Study Group. Diabetes Care. 2001;24:1335-41.