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

Gepubliceerd: 12-09-2005 Laatst bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON24407

Bron
NTR

Verkorte titel
DALI study

Aandoening

Diabetes mellitus type 2.

Ondersteuning

Primaire 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
Overige ondersteuning: Parke Davis, Rotterdam, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

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)
Department of Thrombosis and Haemostasis
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	17-06-1998
Aantal proefpersonen:	217
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-09-2005
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	NL266
NTR-old	NTR304
Ander register	: N/A
ISRCTN	ISRCTN72259862

Resultaten

Samenvatting resultaten

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.