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A double-blind randomised placebo-controlled trial in patients with diabetes mellitus type 2 and hypertriglyceridemia

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
17/12/2015

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

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

Acronym
DALI

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

Ethics approval required
Old ethics approval format

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

Study design
Multicentre randomised double-blind placebo-controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
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 randomised to treatment with atorvastatin 10 mg, 80 mg, or placebo, administered once daily in the morning. Patients randomised to atorvastatin 80 mg started with 40 mg for four weeks after which the dose was increased to 80 mg. The total treatment period was 30 weeks.

Intervention Type
Drug

Phase
Not Applicable

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

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

Secondary outcome measures
The effects on other aspects of diabetic dyslipidemia.

Overall study start date
17/06/1998

Completion date
31/01/2000

Eligibility

Key inclusion criteria
1. Diabetes mellitus type 2 for greater than 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.

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
217

Key exclusion criteria
1. History of myocardial infarction, Percutanerous Transluminal Coronary Angioplasty (PTCA), Coronary Artery Bypass Graft (CABG), clinical symptoms of manifest coronary artery disease (greater than grade II of the Canadian Cardiovascular Society), severe or unstable angina pectoris (greater than grade II), clinically manifest heart failure (greater than grade II New York Heart Association [NYHA]) and severe cardiac arrhythmias
2. Premenopausal women, patients with acute liver disease or hepatic dysfunction, impaired

renal function (plasma creatinine greater than 150 mmol/l), a history of partial ileal bypass surgery, any surgical procedure or any systemic inflammatory disease within the last three months before randomisation, malignancies, vasculitis, rheumatic arthritis, idiopathic lung fibrosis, ulcerative colitis or Crohns 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

Date of first enrolment
17/06/1998

Date of final enrolment
31/01/2000

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Erasmus Medical Centre (Netherlands)

Sponsor details
Dr Molewaterplein 40/50
Rotterdam
Netherlands
3000 CA

Sponsor type
University/education

Website
http://www.erasmusmc.nl/

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Industry

Funder Name
Parke Davis B.V. (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	results	01/08/2001		Yes	No
Results article	results	01/04/2015		Yes	No