

# 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

☐ Prospectively registered

☐ Protocol

**Registration date**  
20/12/2005

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
17/12/2015

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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, Percutaneous 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?
<a href="#">Results article</a>	results	01/08/2001		Yes	No
<a href="#">Results article</a>	results	01/04/2015		Yes	No