

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

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 17/12/2015	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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**

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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

The effects on other aspects of diabetic dyslipidemia.

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

All

**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)

**ROR**  
<https://ror.org/018906e22>

## Funder(s)

**Funder type**  
Industry

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

## Results and Publications

**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
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes