

# Lipids in Diabetes Study

<b>Submission date</b> 31/05/2002	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 31/05/2002	<b>Overall study status</b> Stopped	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/02/2010	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Rury R Holman

### Contact details

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United Kingdom  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

BAY w 6228/200016

## Study information

Scientific Title

**Acronym**

LDS

**Study objectives**

The Lipids in Diabetes Study (LDS) was a prospective, randomised, placebo-controlled, clinical outcome trial which commenced recruitment in April 1999. The principal objective of the trial was to determine whether lipid reduction with a statin (cerivastatin) or a fibrate (fenofibrate) could substantially reduce cardiovascular related morbidity and mortality in subjects with type 2 diabetes (non-insulin dependent diabetes). 4191 people with type 2 diabetes but not known coronary heart disease (CHD) and who were not thought to require lipid lowering therapy were randomised to lipid-lowering therapy with cerivastatin (Lipobay) and fenofibrate (Lipantil) in a two-by-two factorial design in thirty UK clinical centres before cerivastatin was withdrawn. Secondary objectives were to assess the effects of the two study drugs on predefined major clinical events, progression of microalbuminuria, changes in digital electrocardiographic parameters and the lipid profile. The study ended prematurely when Bayer unexpectedly withdrew their cholesterol lowering drug, cerivastatin, in August 2001.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised, placebo-controlled, clinical outcome trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Not Specified

**Participant information sheet****Health condition(s) or problem(s) studied**

Type 2 diabetes

**Interventions**

1. Cerivastatin and placebo
2. Fenofibrate and placebo
3. Cerivastatin and fenofibrate
4. Placebo

**Intervention Type**

Drug

**Phase**

Not Specified

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

cerivastatin

**Primary outcome measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/04/1999

**Completion date**

31/08/2001

**Reason abandoned (if study stopped)**

Objectives no longer viable

**Eligibility****Key inclusion criteria**

Established type 2 diabetics aged between 40 and 75

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

5000

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/04/1999

**Date of final enrolment**

31/08/2001

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

### Diabetes Trials Unit

Oxford

United Kingdom

OX3 7LJ

# Sponsor information

## Organisation

Bayer PLC (UK)

## Sponsor details

Bayer House

Strawberry Hill

Newbury

United Kingdom

RG14 1JA

## Sponsor type

Industry

## Website

<http://www.bayer.co.uk>

## ROR

<https://ror.org/05emrqw14>

# Funder(s)

## Funder type

Industry

## Funder Name

Bayer PLC (UK)

# 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