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Lipids in Diabetes Study

Submission date	Recruitment status	[ ] Prospectively registered
31/05/2002	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
31/05/2002	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/02/2010	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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
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and fenofibrate (Lipantil) in a two-by-two factorial design in thirty UK clinical centres before cerivastatin was withdrawn.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

Primary study design
Interventional

Study design
Randomised, placebo-controlled, clinical outcome trial

Study type(s)
Not Specified

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(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Diabetes Trials Unit
Oxford
United Kingdom
OX3 7LJ

Sponsor information

Organisation
Bayer PLC (UK)

ROR
https://ror.org/05emrqw14

Funder(s)

Funder type
Industry

Funder Name
Bayer PLC (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration