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Lipids in Diabetes Study

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

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and fenofibrate (Lipantil) in a two-by-two factorial design in thirty UK clinical centres before cerivastatin was withdrawn.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