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Apolipoprotein B and low density lipoprotein size in type two diabetes: effect of atorvastatin and gemfibrozil

Submission date	Recruitment status	
08/12/2006	No longer recruiting	[ ] Prospectively registered
Registration date	Overall study status	[ ] Protocol
24/04/2007	Completed	[ ] Statistical analysis plan
Last Edited	Condition category	[X] Results
14/11/2022	Nutritional, Metabolic, Endocrine	[ ] 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
ApoB-DM2

Study information

Scientific Title

Apolipoprotein B and low density lipoprotein size in type two diabetes: effect of atorvastatin and gemfibrozil

Study objectives
Lipid-lowering drugs have complementary and additive effects on the components of diabetic dyslipidaemia and markers of inflammation in type two diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from local Ethics Committee (Fundacio de Gestio Sanitaria de L'Hospital de la Santa Creu i Sant Pau IRB) in late 1998.

Study design
Open-label randomised cross-over trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type two diabetes

Interventions
Patients will receive either:
1. Atorvastatin 10 - 20 mg/d
2. Gemfibrozil 900 - 1200 mg/d
For 12 weeks, and then will receive:
3. 10 mg atorvastatin and 900 mg gemfibrozil combined for 12 additional weeks

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Atorvastatin and gemfibrozil

Primary outcome(s)
Effect on components of diabetic dyslipidaemia (especially apoB and LDL size).

Key secondary outcome(s))
Concentrations of inflammatory markers.

Completion date
01/05/2001

Eligibility

Key inclusion criteria
1. Men and women with type two diabetes, aged 35 to 75 years
2. No treatment known to interfere with lipid metabolism (nonselective B-blockers, high dose diuretics, systemic steroids, lipid-lowering drugs) in the month preceding inclusion in the study
3. Plasma Low Density Lipoprotein cholesterol (LDLc) greater than 100 mg/dl (2.6 mmol/litre), and triglycerides less than 400 mg/dl (4.51mmol/litre)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
44

Key exclusion criteria
1. Pregnant
2. No reliable contraceptive method was used
3. Serum creatinine more than 1.7 mg/dl (150 umol/litre)
4. Hepatic dysfunction (transaminases greater than 1.5 times upper normal limit at inclusion)
5. Creatine kinase more than three times the upper normal limit
6. Acute or chronic disorders that might interfere with compliance

Date of first enrolment
01/05/1999

Date of final enrolment
01/05/2001

Locations

Countries of recruitment
Spain

Study participating centre
Endocrinology Department
Barcelona
Spain
08025

Sponsor information

Organisation
Hospital Sant Pau (Spain)

ROR
https://ror.org/059n1d175

Funder(s)

Funder type
Government

Funder Name
Catalonian Research Board (Spain) (ref: 1999 FI-712)

Funder Name
Fund for Health Research (Fondo de Investigaciones Sanitarias [FIS]) (Spain) (ref: C03/08, PI052099 and PI051540)

Funder Name
Pfizer (Spain) - study drugs and funding for some of the laboratory measurements were provided

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2003		Yes	No