

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

Submission date
08/12/2006

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
24/04/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
14/11/2022

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

Concentrations of inflammatory markers.

Overall study start date

01/05/1999

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

Age group

Adult

Sex

Both

Target number of participants

40

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)

Sponsor details

c/o Antonio Pérez Pérez

Endocrinology Department

S Antonio M Claret 167

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aperez@santpau.es

Sponsor type

Hospital/treatment centre

Website

<http://www.santpau.es/>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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