

# 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

### 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 01/07/2003   |            | Yes            | No              |