# To see if fenofibrate has any advantage over atorvastatin in effects on insulin sensitivity in volunteers with type 2 diabetes

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
25/04/2008	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
15/05/2008	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
12/04/2021	Nutritional, Metabolic, Endocrine	

## 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

Clinical Trials Information System (CTIS)

2007-004935-44

Protocol serial number

RGHTCUR125

# Study information

#### Scientific Title

The effect of the peroxisome proliferator-activated receptor alpha agonist fenofibrate on insulin sensitivity compared to atorvastatin in type 2 diabetes mellitus: A randomised, doubleblind controlled trial

#### **Study objectives**

The peroxisome proliferator-activated receptor alpha agonist fenofibrate may increase insulin sensitivity compared to atorvastatin in type 2 diabetes mellitus.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Local Research and Ethics Committee of the Queen's University of Belfast. Date of approval: 29 /10/2003 (ref: 175/03)

#### Study design

Randomised, double-blind, prospective, two-period cross-over trial.

#### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Type 2 diabetes mellitus, insulin resistance

#### **Interventions**

This is a randomised, cross-over trial.

Treatment 1: Micronised fenofibrate (oral) 267 mg once daily

Treatment 2: Atorvastatin (oral) 10 mg once daily

#### Intervention schedule:

Previous lipid-lowering therapy was withdrawn for 4 weeks prior to assessment for entry eligibility criteria. Subjects then commenced a 4-week placebo run-in after which baseline assessments were carried out. The participants were then randomised to either fenofibrate or atorvastatin in a double-blinded manner and continued for 12 weeks, after which end-point assessments were carried out. A 4-week placebo-controlled washout period followed, and then subjects proceeded to 12 weeks therapy with the alternative blinded therapy (atorvastatin or fenofibrate). End-points were again assessed after this treatment period.

The full period of follow-up of each individual volunteer was 36 weeks, and is broken down as follows:

- 1. 4 week washout period from previous therapy
- 2. 4 week placebo run-in period
- 3. 12 week treatment period 1

- 4. 4 week placebo wash-out period
- 5. 12 week treatment period 2

#### **Intervention Type**

Drug

#### Phase

**Not Specified** 

### Drug/device/biological/vaccine name(s)

Fenofibrate, atorvastatin

#### Primary outcome(s)

Glucose infusion rate required to maintain isoglycaemia in the last 30 minutes of a 2-hour insulin infusion at a rate of 2 mU/kg/minute. This was assessed within three days of the end of each treatment period.

#### Key secondary outcome(s))

The following were assessed within three days of the end of each treatment period:

- 1. Isotopically-determined total body glucose disposal rate and suppression of endogenous glucose production in the last 30 minutes of a 2-hour insulin infusion at a rate of 2 mU/kg/minute
- 2. Serum total, low-density and high density cholesterol and fasting total triglyceride

### Completion date

25/01/2006

# Eligibility

### Key inclusion criteria

- 1. Males and post-menopausal females
- 2. Aged 35-70 years old
- 3. Type 2 diabetes mellitus, clinically well
- 4. On diet or oral anti-diabetic therapy
- 5. Fasting total triglyceride <4.5 mmol/L

# Participant type(s)

Patient

# Healthy volunteers allowed

No

# Age group

Adult

#### Sex

**Not Specified** 

#### Total final enrolment

13

#### Key exclusion criteria

- 1. Age <35 or >70 years
- 2. Total fasting triglycerides pre-treatment or after withdrawal of previous therapy >= 4.5mmol/L
- 3. Total cholesterol >6.5 mmol/L
- 4. Excess alcohol consumption
- 5. Ischaemic heart, peripheral vascular or cerebrovascular disease
- 6. Hepatic disease
- 7. Epilepsy
- 8. Body mass index >35 kg/m<sup>2</sup>
- 9. Pre-menopausal females
- 10. HbA1c >8%
- 11. Current insulin or thiazolidinedione therapy within 6 months
- 12. Significant renal impairment or overt proteinuria (serum creatinine >150 µmol/L, estimated glomerular filtration rate (eGFR) by the Modification of Diet in Renal Disease (MDRD) formula <50 mL/minute, urine spot albumin >200 mg/L, albumin-creatinine ratio >20 mg/mmol or 24-hour urine protein >300 mg)
- 13. Uncontrolled hypertension (>140/80 mmHg)

#### Date of first enrolment

01/06/2004

#### Date of final enrolment

25/01/2006

# Locations

#### Countries of recruitment

United Kingdom

Northern Ireland

## Study participating centre East Wing Office

Belfast United Kingdom BT12 6BA

# Sponsor information

#### Organisation

Belfast Health and Social Care Trust (UK)

#### **ROR**

https://ror.org/02tdmfk69

# Funder(s)

# Funder type

Government

## Funder Name

Research Fellowship Award from the Research and Development Office of the Northern Ireland Department of Health and Social Services (ref: EAT/2197/02)

# **Results and Publications**

Individual participant data (IPD) sharing plan

## 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		01/05/2014	12/04/2021	Yes	No
Abstract results	p.44	20/02/2007		No	No
Abstract results		21/08/2007		No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes