

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

Submission date 25/04/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/05/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/04/2021	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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, double-blind 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)

Primary study design

Interventional

Study design

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

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Previous lipid-lowering therapy was withdrawn for 4 weeks prior to assessment for entry eligibility criteria.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 ≥ 4.5 mmol/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/m²
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 μ mol/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