

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

Registration date

15/05/2008

Overall study status

Completed

Last Edited

12/04/2021

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ 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

EudraCT/CTIS number

2007-004935-44

IRAS number**ClinicalTrials.gov number**

Secondary identifying numbers

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)

Study design

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

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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Previous lipid-lowering therapy was withdrawn for 4 weeks prior to assessment for entry eligibility criteria.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 measure

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.

Secondary outcome measures

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

Overall study start date

01/06/2004

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

Age group

Adult

Sex

Not Specified

Target number of participants

12

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 $>35 \text{ kg/m}^2$
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 $>150 \mu\text{mol/L}$, estimated glomerular filtration rate (eGFR) by the Modification of Diet in Renal Disease (MDRD) formula $<50 \text{ mL/minute}$, urine spot albumin $>200 \text{ mg/L}$, albumin-creatinine ratio $>20 \text{ mg/mmol}$ or 24-hour urine protein $>300 \text{ mg}$)
13. Uncontrolled hypertension ($>140/80 \text{ mmHg}$)

Date of first enrolment

01/06/2004

Date of final enrolment

25/01/2006

Locations**Countries of recruitment**

Northern Ireland

United Kingdom

Study participating centre
East Wing Office
Belfast
United Kingdom
BT12 6BA

Sponsor information

Organisation

Belfast Health and Social Care Trust (UK)

Sponsor details

The Royal Research Office
Education & Research Centre
The Royal Hospitals
Belfast Trust and Social Care Trust
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Sponsor type

Hospital/treatment centre

Website

<http://www.belfasttrust.hscni.net>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Abstract results	p.44	20/02/2007		No	No
Abstract results		21/08/2007		No	No
Results article		01/05/2014	12/04/2021	Yes	No