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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
[X] 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Previous lipid-lowering therapy was withdrawn for 4 weeks prior to assessment for entry eligibility criteria.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 >= 4.5mmol/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^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 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
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
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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