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A pilot study to investigate the effect of pioglitazone on muscle and liver triglyceride content and total body fat in patients with familial combined hyperlipidaemia: relation to parameters of lipid and carbohydrate metabolism

Submission date	Recruitment status	[ ] Prospectively registered
29/07/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/04/2014	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Study objectives
We hypothesise that patients with familial combined hyperlipidaemia will have increased skeletal muscle and liver triglyceride content as well as visceral obesity. Treatment with pioglitazone will improve these abnormalities and the lipid profile as a result of increased insulin sensitivity through its action on the PPAR gamma-receptor.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee approval No. 2002/6480

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Familial Combined Hyperlipidaemia

Interventions
Treatment with pioglitazone versus placebo

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
Skeletal muscle and liver triglyceride content, using 1H Magnetic Resonance Spectroscopy (1H-MRS) and total body fat map: visceral, non-visceral and subcutaneous, using Magnetic Resonance Imaging (MRI)

Key secondary outcome(s))
Parameters of lipid and carbohydrate metabolism: Total cholesterol, triglyceride, HDL cholesterol, LDL cholesterol, total to HDL cholesterol ratio, Non-Esterified Fatty Acids (NEFA), Lipoprotein a (Lp(a)), apolipoprotein A-I, apolipoprotein B, glucose, insulin, leptin

Completion date
30/06/2006

Eligibility

Key inclusion criteria
1. Age between 18-75 years
2. Familial combined hyperlipidaemia (CHL) that fits the above criteria
3. Inadequately controlled with conventional lipid lowering medication, with at least one of the following: total cholesterol >5.0 mmol/l; triglyceride >1.7 mmol/l; HDL-cholesterol <1.0 mmol/l; total cholesterol:HDL cholesterol ratio >5.0
4. Willing and able to comply with the conditions and requirements of the study
5. Signed and dated an informed consent form and be able to comply with the study procedures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. Hyperlipidaemia at diagnosis, secondary to obesity, diabetes mellitus, hypothyroidism, liver or kidney disease
2. Taking medication affecting serum lipids or excessive alcohol intake
3. Other forms of genetic hyperlipidaemia (familial hypercholesterolaemia)
4. Pregnancy
5. MI ('heart attack'), stroke or transient ischaemic attack ('mini stroke') in the previous 6 months
6. Malignant disease (cancer) in the previous 5 years (except basal cell carcinoma)
7. Type 1 or type 2 diabetes mellitus
8. NYHA class II, III or IV (mild, moderate or severe Heart Failure)
9. Alcohol or drug abuse
10. Significant renal (kidney) impairment (creatinine >135 µmol/l)
11. Abnormal liver tests (alanine aminotransferase [ALT] >2.5 times the upper limit of the reference range)
12.Had any alteration in their lipid lowering medication (dose or drug) in the previous 2 months
13. Had treatment with corticosteroids ('cortisol') in the previous 4 weeks (use of topical or inhaled corticosteroids is allowed)
14. Taken another investigational study drug or product within the previous 3 months

15. Donated or received blood or blood products within the previous 3 months
16. Females who are any of the following: Planning pregnancy during the study or breast feeding, or child bearing potential and not planning to use a reliable method of contraception throughout the study (e.g. oral contraception)
17. Any other condition or circumstance that, in the opinion of the investigator, may compromise the patient's ability to comply with the study protocol
18. An inability to tolerate MRI/MRS scanning (claustrophobia)
19. Standard contraindications for MRI/MRS scanning (e.g. cardiac pacemaker, mechanical heart valve, history of foreign body in the eye, IUCD, haemostatic clips, metal prosthesis, orthopaedic plates, occupation as metal worker, welder etc.)

Date of first enrolment
18/12/2002

Date of final enrolment
30/06/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MRC Clinical Sciences Centre
London
United Kingdom
W12 0NN

Sponsor information

Organisation
Medical Research Council (UK)

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council and J Coller Foundation (UK)

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	results	01/11/2007		Yes	No