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

Contact name

Dr Rossi Naoumova

Contact details

MRC Clinical Sciences Centre Hammersmith Hospital Du Cane Road London United Kingdom W12 ONN

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

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)

Secondary outcome measures

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

Overall study start date

18/12/2002

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

26

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

England

United Kingdom

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

Sponsor information

Organisation

Medical Research Council (UK)

Sponsor details

Clinical Sciences Centre Hammersmith HospitalMedical Du Cane Road London United Kingdom W12 0NN

Sponsor type

Research council

Website

http://www.mrc.ac.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

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 typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results articleresults01/11/2007YesNo