

Randomised double-blind placebo controlled trial of treatment with pioglitazone in non-alcoholic steatohepatitis

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/03/2011	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr GP Aithal

Contact details
D Floor
South Block
University Hospital
Nottingham
United Kingdom
NG7 2UH
+44 0115 924 9924 (ext 65747)
guru.aithal@mail.qmcuh-tr.trent.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0192119052

Study information

Scientific Title

Study objectives

Does pioglitazone improve necro-inflammation associated with non-alcoholic steatohepatitis (NASH)?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 27/03/08:

Approved by Nottingham Joint Ethics Committee, ref GM050201, 25/11/2002.

Study design

Randomised double-blind placebo controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

Digestive System: Liver

Interventions

Pioglitazone vs placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

pioglitazone

Primary outcome measure

Necro-inflammation and fibrosis score on liver biopsy.

Secondary outcome measures

1. Liver enzymes
2. Clinical and biochemical parameters of metabolic syndrome

Overall study start date

25/11/2002

Completion date

31/12/2007

Eligibility

Key inclusion criteria

Added 27/03/08:

1. Age 18-70 years
2. Histological evidence of NASH

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

Total number of subjects = 124. Number as of 28/03/07: 75

Key exclusion criteria

Added 27/03/08:

1. Alcohol consumption >21 units in males and >14 units in females
2. Diabetes Mellitus
3. Consumption of drugs that cause fatty liver
4. Other liver diseases (clinical or on liver biopsy)

Date of first enrolment

25/11/2002

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**D Floor**

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

Queens Medical Centre University Hospital NHS Trust (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 type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2008		Yes	No