

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

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 10/03/2011	Condition category Digestive System	☐ 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

Protocol serial number

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.

Primary study design

Interventional

Study design

Randomised double-blind placebo controlled trial

Study type(s)

Treatment

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(s)

Necro-inflammation and fibrosis score on liver biopsy.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

All

Key exclusion criteria

Added 27/03/08:

1. Alcohol consumption >21units 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

United Kingdom

England

Study participating centre

D Floor

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Queens Medical Centre University Hospital NHS Trust (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	01/10/2008		Yes	No