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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 10/03/2011	**Condition category** Digestive System	

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.

Study design
Randomised double-blind placebo controlled trial

Primary study design
Interventional

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes