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The biological variation of insulin resistance and cardiovascular risk factors in patients with non-alcoholic fatty liver disease compared to type 2 diabetes

Submission date 27/04/2009	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 13/05/2009	**Overall study status** Stopped	
Last Edited 18/06/2013	**Condition category** 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

R0783

Study information

Scientific Title
The biological variation of insulin resistance and cardiovascular risk factors in patients with non-alcoholic fatty liver disease compared to type 2 diabetes: an observational prospective study

Acronym
BV NASH-T2DM

Study objectives
Patients with Non-alcoholic Fatty Liver Disease (NAFLD) have at least as great intra-individual variance of insulin resistance measured using the homeostasis model assessment (HOMA-IR) as those with the paradigm of insulin resistance; Type 2 Diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hull and East Riding Research Ethics Committee, approved on 13/03/2009 (ref: LREC 09/H1304 /2).

Study design
Observational prospective cross-sectional study

Primary study design
Observational

Secondary study design
Cross-section survey

Study setting(s)
Hospital

Study type(s)
Other

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
Non-alcoholic fatty liver disease and type 2 diabetes

Interventions
18/06/2013: Please note that this trial was stopped in April 2011.

Twenty type 2 diabetes patients and 20 NAFLD/NASH patients will be recruited for this study (total n = 40).

Over 5 weeks fasting blood samples taken to determine the biological variation of insulin resistance and clotting structure and function and on one occasion endothelial function will be measured using Endo-PAT2000® in the 2 groups - NASH/NAFLD and type 2 diabetes.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To determine the biological variation of insulin resistance measured by HOMA in patients with NAFLD compared to type 2 diabetes.

Secondary outcome measures
1. To show statistically significant greater intra-individual variance of insulin resistance measured by HOMA in patients with NASH
2. To determine the level of endothelial dysfunction in subjects with NASH compared to NAFLD compared to type 2 diabetes
3. To determine the fibrin clot structure and function in subjects with NAFLD/NASH compared to type 2 diabetes

Overall study start date
14/04/2009

Completion date
30/09/2010

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
For both groups:
Both males and females, over age of 16 years

For NAFLD/non-alcoholic steatohepatitis (NASH) group:
1. Patients with confirmed NAFLD/NASH
2. Able to give informed consent
3. Agreeing to consent to inform GP's regarding participation in the study
4. No change in medication for 3 months prior to starting the study

For type 2 diabetes group:
1. Diabetes diagnosed according to World Health Organization (WHO) criteria
2. No change in medication for 3 months prior to starting study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
For NAFLD/NASH group:
1. Patients with concurrent illnesses
2. Patients not wishing to allow disclosure to their GP's
3. Alcohol intake more than 14 units/week for women, 21 units a week for men
4. Diabetic patients
5. Pregnancy or breastfeeding women
6. Smokers

For type 2 diabetes group:
1. Abnormal results from liver function tests (LFTs)
2. Patients with concurrent illnesses
3. Patients not wishing to allow disclosure to their GP's
4. Alcohol intake more than 14 units/week for women, 21 units a week for men
5. Pregnancy or breastfeeding women
6. Smokers

Date of first enrolment
14/04/2009

Date of final enrolment
30/09/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
HS Brocklehurst Building
Hull
United Kingdom
HU3 2RW

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

Sponsor details
Daisy Building
Castle Hill Hospital
Cottingham
England
United Kingdom
HU16 5JQ

Sponsor type
Hospital/treatment centre

Website
http://www.hey.nhs.uk

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
University/education

Funder Name
Diabetes Endowment Fund, University of Hull (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