

# 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

**Registration date**

13/05/2009

**Overall study status**

Stopped

☐ Statistical analysis plan

☐ Results

**Last Edited**

18/06/2013

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Stephen Atkin

### Contact details

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## Additional identifiers

**Protocol serial number**

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).

**Primary study design**

Observational

**Study design**

Observational prospective cross-sectional study

**Study type(s)**

Other

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

HS Brocklehurst Building

Hull

United Kingdom

HU3 2RW

## **Sponsor information**

**Organisation**

Hull and East Yorkshire Hospitals NHS Trust (UK)

**ROR**

<https://ror.org/01b11x021>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

Diabetes Endowment Fund, University of Hull (UK)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration