

# A pilot study to determine if the Glyco Liver Profile is a suitable blood test for measuring liver inflammation in non-alcoholic steatohepatitis (NASH) patients

<b>Submission date</b> 08/07/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/07/2022	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Non-alcoholic fatty liver disease (NAFLD) is a common liver disease present in about 25% of the adult population of the UK. 80% of people with NAFLD will not develop significant liver disease. However, in 20% of people, liver disease may progress to liver inflammation (NASH), cirrhosis and/or liver cancer. Doctors are currently unable to diagnose active liver inflammation (NASH) in NAFLD without a liver biopsy, an invasive procedure that carries a significant risk of pain and bleeding. Glyco Liver Profile is a blood test designed to measure liver inflammation without the need for a liver biopsy. It is due to be fully licensed for use in the NHS in the UK in January 2019. It is envisaged that the test would be used to aid the identification of active NASH in the NAFLD patient group. Clinical drug trials for NASH are currently recruiting participants and methods to identify people who may benefit from new drug treatments without the need for liver biopsy are urgently required. The Glyco Liver Profile blood test could avoid unnecessary invasive testing and help identify a cohort of patients who could be considered for recruitment into NASH clinical trials and may be eligible for NASH medicines once licensed. The aim of this study is to find out whether the Glyco Liver Profile is a suitable blood test for measuring liver inflammation in non-alcoholic steatohepatitis (NASH) patients.

### Who can participate?

Patients with NAFLD who are having or not having a liver biopsy, and patients who don't have NAFLD

### What does the study involve?

Participants are asked to provide one blood sample at the same time as their routine clinical blood samples. Only 5 ml (one teaspoon of blood) is taken for study purposes. Participants are asked some questions (not a questionnaire but data collection form only) about their medical history and medications which does not take longer than 30 minutes. There is no further follow up.

What are the possible benefits and risks of participating?

There will be no direct benefit to participation. However, it is hoped that this study will help to improve care for patients with non-alcoholic fatty liver disease. The result of the Glyco Liver Profile blood test will be entered into the patients' medical records and this may be of interest to the patient and add to the test results available to the liver doctor. No significant risks are expected. Only 5 ml (one teaspoon of blood) will be taken for study purposes. This blood sample will be destroyed after analysis. The patient will be asked some questions about medical history and medications which will not take longer than 30 minutes. There will be no further trial-specific intervention or follow up.

Where is the study run from?

Hull and East Yorkshire Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?

April 2019 to April 2020

Who is funding the study?

Helena Biosciences Europe Limited

Who is the main contact?

Dr Lynsey Corless

lynsey.corless@nhs.net

## Contact information

### Type(s)

Scientific

### Contact name

Dr Lynsey Corless

### Contact details

Hull and East Yorkshire Hospitals NHS Trust

8th Floor Alderson House

Hull Royal Infirmary

Hull

United Kingdom

HU3 2JZ

+44 (0)1482816776

lynsey.corless@nhs.net

### Type(s)

Scientific

### Contact name

Mrs Nurun Tania

### Contact details

Hull and East Yorkshire Hospitals NHS Trust

8th Floor Alderson House

Hull Royal Infirmary

Hull  
United Kingdom  
HU3 2JZ  
+44 (0)1482675081  
nurun.tania@nhs.net

## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

CPMS: 41256

## **Study information**

### **Scientific Title**

A pilot study to determine if the Glyco Liver Profile is a suitable candidate assay for measuring liver inflammation in non-alcoholic steatohepatitis (NASH) patients

### **Study objectives**

NAFLD is a common liver disease present in about 25% of the adult population of the UK. 80% of people with NAFLD will not develop significant liver disease. However, in 20% of people, liver disease may progress to liver inflammation (NASH), cirrhosis and/or liver cancer. We are currently unable to diagnose active liver inflammation (NASH) in NAFLD without a liver biopsy, an invasive procedure that carries a significant risk of pain and bleeding.

Glyco Liver Profile is a blood test designed to measure liver inflammation without the need for a liver biopsy. It is due to be fully licensed for use in the NHS in the UK in January 2019. It is envisaged that the test would be used to aid the identification of active NASH in the NAFLD patient group. Clinical drug trials for NASH are currently recruiting participants and methods to identify people who may benefit from new drug treatments without the need for liver biopsy are urgently required.

The Glyco Liver Profile blood test could avoid unnecessary invasive testing and help identify a cohort of patients who could be a) considered for recruitment into NASH clinical trials and b) may be eligible for NASH medicines once licensed.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 05/04/2019, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; Tel: +44 (0)207 1048 088; Email: nrescommittee.yorkandhumber-bradfordleeds@nhs.net), ref: 19/YH/0037

## **Study design**

Non-randomised; Observational; Design type: Cohort study

## **Primary study design**

Observational

## **Secondary study design**

Cohort study

## **Study setting(s)**

Hospital

## **Study type(s)**

Diagnostic

## **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

## **Health condition(s) or problem(s) studied**

Nonalcoholic steatohepatitis (NASH)

## **Interventions**

Patients with a diagnosis of NAFLD prospectively attending the liver clinic will be approached and asked if they would like to participate. If in agreement, they will be asked to sign a consent form. The researchers will also approach people without NAFLD who are attending a general gastroenterology clinic, to act as the normal sample group. Participation will involve an additional blood sample (5 ml) being taken at the time of routine clinical care sample collection. Participants will be asked some questions (not a questionnaire but data collection form only) about their medical history and medications which will not take longer than 30 minutes. There will be no further follow up. No other involvement or activity will be required from participants. The sample will be processed in the laboratory with routine clinical samples. The test result will return to the study team, who will store the result alongside demographic and biochemical information on an anonymised, password-protected database. The test result will also be documented in the medical records.

## **Intervention Type**

Other

## **Primary outcome measure**

1. Journey mapping of the sample from clinic to lab to final result, to demonstrate logistical feasibility
2. Patient acceptability of having the test, assessed by direct questioning

## **Secondary outcome measures**

Analysis of participants' Glyco and liver biopsy results, alongside other clinical data, to determine if there is preliminary evidence of correlation (not statistically powered)

**Overall study start date**

22/01/2019

**Completion date**

11/12/2020

## **Eligibility**

**Key inclusion criteria**

1. 18 years or older on day of consent
2. Must be diagnosed with NAFLD with no liver biopsy planned (group 1)  
or  
Must be diagnosed with NAFLD with a planned liver biopsy (group 2)  
or  
Must not have a diagnosis of NAFLD (group 3)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 30; UK Sample Size: 30

**Total final enrolment**

36

**Key exclusion criteria**

1. Must be less than 80 years old on day of consent
2. Unable to provide informed consent
3. Must not have a confirmed diagnosis of any liver disease other than NAFLD (group 1 and 2)
4. Must not have a diagnosis of any liver disease (group 3)

**Date of first enrolment**

11/06/2019

**Date of final enrolment**

01/04/2020

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Hull and East Yorkshire Hospitals NHS Trust**

Hull Royal Infirmary

Anlaby Road

Hull

United Kingdom

HU3 2JZ

**Sponsor information****Organisation**

Hull University Teaching Hospitals NHS Trust

**Sponsor details**

Hull Royal Infirmary

Anlaby Road

HULL

England

United Kingdom

HU3 2JZ

+44 (0)1482675081

bronwen.williams@hey.nhs.uk

**Sponsor type**

Hospital/treatment centre

**ROR**

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

**Funder(s)****Funder type**

Industry

**Funder Name**

Helena Biosciences Europe Limited

# Results and Publications

## Publication and dissemination plan

1. Peer-reviewed scientific journals
2. Conference presentation
3. Hospital Trust and Yorkshire and Humber Liver Network newsletters

## Intention to publish date

11/12/2021

## Individual participant data (IPD) sharing plan

Data collected will be anonymised using a unique study number and will be the only identifier on the data collection form. Only the research team will know who the data belongs to. The data collected will be securely stored at the study office at Hull University Teaching Hospital. All information collected about the patient for this study will be subject to the General Data Protection Regulation and Data Protection Act 2018 for health and care research and will be kept strictly confidential. The researchers will be using information from the patient and/or medical records in order to undertake this study and will act as the data controller for this study. Hull University Teaching Hospital will keep identifiable information about the patient for 5 years after the study has finished. Hull University Teaching Hospital will keep the patient's name, NHS number and contact details confidential and will not pass this information to any other organisation. Hull University Teaching Hospital will use this information as needed, to contact participants about the research study, and make sure that relevant information about the study is recorded for care, and to oversee the quality of the study. Certain individuals from Hull University Teaching Hospital and regulatory organisations may look at participants' medical and research records to check the accuracy of the research study. These people will only receive information without any identifying information. The people who analyse the information will not be able to identify participants and will not be able to find out their names, NHS numbers or contact details. No individual participant will be identified in any publication.

## IPD sharing plan summary

Other

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version V1	21/12/2018	19/08/2019	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No