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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

Submission date
08/07/2019

Recruitment status
No longer recruiting

Registration date
19/08/2019

Overall study status
Completed

Last Edited
19/07/2022

Condition category
Digestive System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
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Contact information

Type(s)
Scientific

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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
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Sponsor information

Organisation
Hull University Teaching Hospitals NHS Trust

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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?
Protocol file	version V1	21/12/2018	19/08/2019	No	No
HRA research summary			28/06/2023	No	No