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LiverMultiscan - replacing liver biopsy

Submission date
11/12/2013

Recruitment status
No longer recruiting

Registration date
27/01/2014

Overall study status
Completed

Last Edited
04/04/2024

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Chronic liver disease is a major contributor to ill health in western society and is the fifth biggest killer in England and Wales. In the UK it is the only major cause of death that is becoming more common. The health problems associated with chronic liver disease are mainly due to scarring in the liver, which is known as fibrosis. The current best method for assessing fibrosis is a liver biopsy. This is where a needle is used to take a sample of liver tissue to be analysed in the lab. A liver biopsy can be used to tell your doctor about the possible cause for liver damage and how bad that damage is. Having a liver biopsy is uncomfortable and carries a small but significant risk. This risk means that it is not often justified to repeat biopsies to monitor progress in liver damage over time or to monitor a patients response to treatment. There are several techniques to assess liver damage without a biopsy but at the moment these are not as reliable as a liver biopsy. The main problem with these non-invasive methods of assessing fibrosis are that they have a limited ability to detect the early stages of fibrosis, where patients have the most to gain. This study aims to assess a new magnetic resonance imaging (MRI) technique called LiverMultiscan for the staging and long-term monitoring of chronic liver disease. There are three strands to this study. The first is called Comprehensive Assessment of the Liver with MRI (CALM). This compares LiverMultiscan with liver biopsy. The second and third are called Longitudinal Assessment with MRI in PSC (LAMP) and Longitudinal Assessment with MRI in Autoimmune Liver Disease (LAMALD). These look at the ability of LiverMultiscan to track the progression of autoimmune liver disease.

Who can participate?
CALM: men or women aged 18 or over having a liver biopsy as part of their routine care to investigate a known or suspected liver condition.
LAMP/LAMALD: men or women aged 18 or over with autoimmune liver disease who do not need a biopsy.

What does the study involve?
CALM: we will offer a LiverMultiscan to patients who are having a liver biopsy as part of their routine care. We will compare the data from the LiverMultiscan with the results from the biopsy. Participants will also have a blood test and a quick, painless ultrasound scan called a Fibroscan.
LAMP/LAMALD: we will offer a LiverMultiscan to patients who have autoimmune liver disease. This includes conditions such as primary sclerosing cholangitis (PSC), primary biliary cirrhosis (PBC) and autoimmune hepatitis. People taking part in this part of the study do not need a liver

biopsy. We will ask these people to attend for a LiverMultiscan at the start of the study and again 18 months later to see if LiverMultiscan can track any changes in the liver over time.
In each part of the study patients will continue with their routine care throughout. No one will miss out on any treatment by taking part.

What are the possible benefits and risks of participating?
There is no immediate benefit to taking part; however, this study may develop a technique that could benefit you or others in the future by making the assessment and monitoring of liver disease quicker and safer. MRI scans are safe and painless and so there are no risks to taking part in this project.

Where is the study run from?
CALM is being carried out between the Universities of Birmingham and Edinburgh. The lead centre is Birmingham and the project will be co-ordinated from there. LAMP/LAMALD take place in Birmingham only.

When is the study starting and how long is it expected to run for?
We started recruiting people to the study in January 2014. The study will continue until September 2018.

Who is funding the study?
The CALM & LAMP studies are funded by the UK's innovation agency, the Technology Strategy Board. LAMALD is funded by the NIHR Rare Diseases Translation Research Collaboration.

Who is the main contact?
Dr Katherine Arndtz (Clinical Research Fellow)
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Contact information

Type(s)
Scientific

Contact name
Dr Gideon Hirschfield

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RG_13-260

Study information

Scientific Title
LiverMultiscan - replacing liver biopsy: an observational study

Study objectives
LiverMultiscan is a novel magnetic resonance imaging (MRI) technique that aims to quantify fibrosis, steatosis and siderosis in the liver.

Our hypothesis is that LiverMultiscan can accurately characterise fibrosis, steatosis and siderosis when compared to the current gold standard, liver biopsy histology.

In this study we will test this hypothesis by comparing the data generated by LiverMultiscan with the gold standard for assessing liver fibrosis, steatosis and siderosis, which is liver biopsy histology. We will also compare LiverMultiscan with other non-invasive markers of chronic liver disease such as blood biomarkers and Fibroscan.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Black Country Research Ethic Committee, 09/01/2014, IRAS reference number: 140543, REC ref: 14/WM/0010

Study design
Two centre cross-sectional observational study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Known or suspected liver disease

Interventions
MRI scan. For this scan participants will fill in a MRI safety questionnaire to ensure there is no risk from the scan and then lie in a comfortable position in the scanner. The scan takes around 30 minutes to complete. Participants will need to lie still and hold their breath for short periods of time while the pictures are taken. We will measure the amount of fibrosis, fat and iron in the liver.

Fibroscan. This is a painless and quick ultrasound technique for measuring the stiffness of the liver. Participants will live on their back with the right arm behind the head. The probe is put against the skin on the right side of the tummy for about 5 minutes while the readings are taken.

Blood tests. These are routine tests of liver and kidney function as well as some blood markers of liver disease. We will try and take these tests at the same time as participants have clinically necessary blood tests to cut down on the number of needles.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Correlation between the MRI result and liver biopsy histology

For CALM the primary outcome measure is the correlation between the MRI result and liver biopsy histology. We will compare the results from participants' MRI scan with the results from their liver biopsy. There is no follow up in the main part of the study. There will be a single MRI scan and a single liver biopsy done as close together as possible.

For LAMP/LAMALD the primary outcome measure is changes on the MRI scan over time. There will be two MRI scans: the first on study entry and the second 18 months later.

Secondary outcome measures
Correlation between MRI results and other non-invasive markers of liver disease such as blood markers and Fibroscan.
We will assess how well LiverMultiscan compares to blood markers and Fibroscan in the diagnosis of liver disease. There is no follow up and all investigations will be done as close together as possible.

Overall study start date
01/01/2014

Completion date
01/09/2018

Eligibility

Key inclusion criteria
CALM: Men and women aged 18 or over who are having a liver biopsy as part of their routine care.

LAMP/LAMALD: Men and women aged 18 or over with an autoimmune liver disease.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150 patients for CALM, 30 patients for LAMP, 180 patients for LAMALD

Total final enrolment
161

Key exclusion criteria
1. Unable or unwilling to give informed consent
2. Liver biopsy targeted at a distinct liver lesion
3. Any contraindication to MRI

Date of first enrolment
01/01/2014

Date of final enrolment
01/04/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Research Support Group
Finance Office
Aston Webb, B Block
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Technology Strategy Board (UK) Ref: 101679

Alternative Name(s)
TSB

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
NIHR Rare Disease Translational Research Collaboration

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/06/2018	10/10/2019	Yes	No
HRA research summary			28/06/2023	No	No
Results article		03/04/2024	04/04/2024	Yes	No