

# LiverMultiscan - replacing liver biopsy

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<b>Registration date</b> 27/01/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/04/2024	<b>Condition category</b> Digestive System	<input type="checkbox"/> 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)  
k.arndtz@bham.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr Gideon Hirschfield

### Contact details

Centre for Liver Research  
Institute of Biomedical Research  
University of Birmingham  
Edgbaston  
Birmingham  
United Kingdom  
B15 2TT

## Additional identifiers

### Protocol serial number

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

## Study type(s)

Diagnostic

## 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 lie 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(s)**

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.

**Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

University of Birmingham

Birmingham

United Kingdom

B15 2TT

**Sponsor information****Organisation**

University of Birmingham (UK)

**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

**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?
<a href="#">Results article</a>	results	15/06/2018	10/10/2019	Yes	No
<a href="#">Results article</a>		03/04/2024	04/04/2024	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No