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A precision and reproducibilty assessment of liver fat measurement by chemical shift magnetic resonance scanning

Submission date 28/04/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 01/07/2016	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/03/2020	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background & Aims
The gold standard technique for non-invasive measurement of liver fat has previously been Magnetic Resonance Spectroscopy. This tool is largely confined to the research setting as it requires high energy scanners which are resource intensive. Chemical Shift Magnetic Resonance (CS-MR) poses an alternative which is more applicable in the clinical setting as it can be used on conventional clinical Magnetic Resonance scanners. The accuracy with which CS-MR can repeatedly measure liver fat levels has not previously been assessed. This study aims to assess liver fat levels by using CS-MR in 10 patients on two occasions separated by a minimum of 24 hours. In this time, actual liver fat levels will not have changed. Statistical analysis will then be performed to determine the variation in results CS-MR produces between scans in the same patients. This will provide information on whether CS-MR can be used in studies and clinical practice to accurately detect changes in liver fat levels.

Who can participate?
Anybody over the age of 18 years old with a body mass index greater than 25.

What does the study involve?
Each participant is asked to attend Royal Blackburn Hospital on 2 occasions. During the first visit they are asked to provide a blood sample to assess liver function, circulating blood fat levels and sugar level control. The participants also have a short chemical shift magnetic resonance scan. On the second visit 4 weeks later another chemical shift magnetic resonance scan is performed.

What are the possible benefits?
There are no perceived benefits to participants. Travel expenses will be reimbursed.

When is the study starting?
October 2015 to August 2017

Who is funding the study?
Rosemere Cancer Foundation (UK)

Where is the study running?
East Lancashire Hospitals NHS Trust, Blackburn (UK)

Who is the main contact?
1. Mr Daren Subar (scientific)
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Additional identifiers

Protocol serial number
Study Protocol v2.0

Study information

Scientific Title
A precision and reproducibility assessment of intra-hepatic fat quantification by chemical shift magnetic resonance

Acronym
LiverPRIMEi

Study objectives
The aim of the study is to determine if chemical shift magentic resonance provides a precise and reproducible method of quantifiying intra-hepatic fat fraction using a clinical magentic resonace scanner.

Null Hypothesis:
1. There is no agreement between repeated quantifications of intra-hepatic fat fraction as measured by chemical shift magnetic resonance

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Observational

Study design
Single centre. Observational feasibility study.

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Hepatic steatosis (fatty liver disease) and non-alcoholic fatty liver disease

Interventions
10 participants will undergo 2 chemical shift magnetic resonance scans using the clinical magnetic resonance scanner at Royal Blackburn Hospital.

These scans will be performed at least one day apart.

On visit 1, participants will also be asked to provide a blood sample for assessment of liver function, glycaemic control and lipid profile. Weight, height and hip-to-waist ratio will also be recorded. From this body mass index will be calculated.

No further blood samples will be acquired on the second visit.

Intra-person results will be statistically analysed for agreement using the Bland Altmann method with a priori variance levels of 0.2 deemed acceptable.

Intervention Type
Device

Primary outcome(s)
Intrahepatic fat fraction as measured by 2 Chemical Shift Magnetic Resonance scans greater than 24 hours apart.

Key secondary outcome(s)
1. Indocyanine Green Plasma Disappearance Rate and Retention at 15 minutes, measured using a PULSiON Indocyanine Green Clearance Testing Device. This will be measured at visit 1 and 4 weeks later
2. BMI, Height, Weight and Hip to Waist ratio, measured at visit 1 and 2
3. Assessment of Liver function, Glycaemic control and Lipid profile, including Bilirubin, AST, ALT, ALP GGT, HbA1c, Random Glucose, Triglycerides and Cholesterol at visit 1.

Completion date
08/08/2017

Eligibility

Key inclusion criteria
1. Participants must be able to receive and understand verbal and written information regarding the study and give written, informed consent.
2. Participants should have features associated with intra-hepatic fat such as elevated BMI.
3. >18 years old
4. Male or female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Persons under 18 years of age
2. Conditions in which the supine position and breath holds required for MR scanning are not possible
3. Persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs
4. Persons with contraindications to MR imaging- presence of cardiac pacemaker/artificial heart valve/aneurysm clips/metallic fragments in eyes/cochlear implants
5. Pre-existing chronic liver pathology such as haemachromatosis, viral hepatitis or primary hepatic malignancy

Date of first enrolment
01/06/2016

Date of final enrolment
01/07/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
East Lancashire Hospitals NHS Trust
Royal Blackburn Hospital
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Sponsor information

Organisation
East Lancashire Hospitals NHS Trust

ROR
https://ror.org/002pa9318

Funder(s)

Funder type
Charity

Funder Name
Rosemere Cancer Foundation

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request