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Comparing imaging techniques in the management of liver disease

Submission date
17/03/2016

Recruitment status
No longer recruiting

Registration date
17/03/2016

Overall study status
Completed

Last Edited
05/09/2023

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
Liver disease refers to a group of conditions which prevent the liver from working as well as it should do. The liver is the second largest organ in the body, performing a number of vital functions. It is responsible for removing toxins (poisons) from the body, releasing bile (a liquid that helps to break down fat during digestion) and helps blood to clot. There are over 100 different types of liver disease, and there are often no obvious symptoms until the liver is already badly damaged. In most types of liver disease, the liver becomes extensively scarred (fibrosis), which if left untreated can lead to complete liver failure. Although a biopsy (taking a tissue sample) is often needed to diagnose liver disease, ultrasound scanning is also widely used in diagnosis and monitoring. This is a safe and painless procedure that uses the way sound waves bounce off different types of tissue inside the body to produce a picture on a screen. Transient elastography (TE) is a scanning technique used to measure the stiffness of the liver. A probe placed on the skin produces a wave of vibration called a 'shear wave'. The time that it takes for this wave to travel to a particular depth in the liver is measured and used to calculate the liver stiffness. If the liver is scarred (fibrosis), then it takes longer for the shear wave to travel through the tissue. Fibroscan (an ultrasound machine made by Echosens) is currently the best technique for detecting liver disease (gold standard), however there are other ultrasound systems available. This study will determine the reliability of Philips Affiniti Elast PQ Ultrasound System for the assessment of liver fibrosis, by comparing it to two other systems (Siemens ARFI Acuson S2000 Ultrasound System and the Fibroscan system made by Echosens).

Who can participate?
Adults with long-term (chronic) liver disease who is about to have, or has recently had, a sample of tissue taken from their liver (biopsy).

What does the study involve?
All participants undergo three ultrasound scans of their liver using the Philips EPIQ 7™ Ultrasound System, the Siemens Acuson (ARFI) Ultrasound System, and by Echosens Fibroscan™ (which is currently the best technique – gold standard). The results of the three scans are then compared to liver biopsy results of the patients in order to find out which is the most accurate technique.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
St. Mary's Hospital, London (UK)

When is the study starting and how long is it expected to run for?
March 2016 to March 2018

Who is funding the study?
Philips Ultrasound Inc. (UK)

Who is the main contact?
1. Ms Claire Parsonage (public)
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2. Professor Simon Taylor-Robinson (scientific)
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20729

Study information

Scientific Title
The role of ultrasound shear wave elastography in the management of liver disease

Study objectives
The aim of this study is to correlate liver stiffness assessed by the Philips EPIQ 7™ Ultrasound System, the Siemens Acuson (ARFI) ultrasound system, and by Fibroscan™ (which is currently the best validated technique), and compare the results of these 3 imaging techniques to histological results in patients with chronic liver disease of different aetiologies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Cambridge East Research Ethics Committee, 03/12/2015, ref: 15/EE/0420

Study design
Single-centre non-randomised diagnostic accuracy study

Primary study design
Interventional

Secondary study design
Non randomised 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
Topic: Hepatology; Subtopic: Hepatology; Disease: All Hepatology

Interventions
Imaging using the Philips EPIQ 7™ Ultrasound System, the Siemens Acuson (ARFI) Ultrasound System, and by Echosens Fibroscan™ (which is currently the best validated technique).

Intervention Type
Other

Primary outcome measure
To correlate liver stiffness assessed by the Philips EPIQ 7™ Ultrasound System, the Siemens Acuson (ARFI) ultrasound system, and by Echosens Fibroscan™ (which is currently the best validated technique), and compare the results of these 3 imaging techniques to histological results in patients with chronic liver disease of different aetiologies.

Secondary outcome measures
1. Cut-off values of the liver stiffness (LS) measurements that correlate to the histological fibrosis stage
2. Variations of the liver stiffness (LS) measurements correlated to different parameters
3. Quality parameters (IQR and SR) for the liver stiffness (LS) measurements
4. Ability of distinguishing non-alcoholic steatohepatitis (NASH) from non-alcoholic fatty liver disease (NAFLD)

Overall study start date
03/03/2016

Completion date
31/05/2018

Eligibility

Key inclusion criteria
1. Able and willing to provide written informed consent
2. Aged between 18 and 75
3. Chronic liver disease
4. About to undergo a liver biopsy as part of standard routine clinical care, or if a liver biopsy has recently been performed, and is willing to come in for a specific research visit for the 3 scans
5. Willing to consent to medical notes and diagnostic test results being reviewed, captured, and recorded by the clinical research study team

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size 100

Total final enrolment
155

Key exclusion criteria
1. Unable or unwilling to give written informed consent
2. Aged under 18 or over 75
3. No evidence of liver disease
4. Pregnancy
5. Patients with pacemakers fitted

Date of first enrolment
03/03/2016

Date of final enrolment
22/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St. Mary's Hospital
Praed Street
London
United Kingdom
W2 1PE

Sponsor information

Organisation
Imperial College London

Sponsor details

Joint Research Compliance Office
Charing Cross Hospital
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Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Industry

Funder Name
Philips Ultrasound Inc.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal in 2019.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	30/11/2015	11/10/2022	No	No
HRA research summary			28/06/2023	No	No
Other	Use of Fibroscan to diagnose hepatic steatosis	09/06	05/09		

publications		/2023	/2023	Yes	No
Other publications	Use of Philips Affinit 70 (ElastPQ) to assess liver and spleen stiffness in patients with and without clinically significant portal hypertension	27/11 /2020	05/09 /2023	Yes	No
Other publications	Use of Philips EPIQ7 to assess liver and spleen stiffness in three groups of patients with HIV infection	01/11 /2019	05/09 /2023	Yes	No