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Comparison between imaging methods (ultrasound and computed tomography) in non-alcoholic fatty liver disease

Submission date	Recruitment status	[ ] Prospectively registered
03/04/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/04/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/05/2021	Digestive System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Non-alcoholic fatty liver disease (NAFLD) is the term for a range of conditions caused by a build-up of fat in the liver. It's usually seen in people who are overweight or obese. A healthy liver should contain little or no fat. It's estimated up to 1 in every 3 people in the UK has early stages of NAFLD, where there are small amounts of fat in their liver. Early-stage NAFLD does not usually cause any harm, but it can lead to serious liver damage, including cirrhosis, if it gets worse.
NAFLD is often diagnosed after a blood test called a liver function test produces an abnormal result and other liver conditions, such as hepatitis, are ruled out. But blood tests do not always pick up NAFLD. The condition may also be spotted during an ultrasound scan or CT scan. Ultrasound is a type of scan where sound waves are used to create an image of the inside of your body. A CT scan or computed tomography scan (formerly known as a computed axial tomography or CAT scan) is a medical imaging technique used in radiology to get detailed images of the body noninvasively for diagnostic purposes.

The aim of the study is to perform a comparison between ultrasound elastography and non-enhanced computed tomography (NECT) for diffuse fatty liver diseases.

Who can participate?
Non-alcoholic patients who have been referred by the physician to have NECT abdomen and diagnosed to have fatty liver and other patients referred for NECT abdomen for any other reasons who don’t have fatty changes in the liver.

What does the study involve?
Imaging the liver of healthy volunteers and study group population for detection of fatty liver.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Saveetha Medical College and Hospital (India)

When is the study starting and how long is it expected to run for?
November 2018 to November 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Comparison between ultrasound elastography and non-enhanced computed tomography Hounsfield units for diffuse fatty liver diseases in non-alcoholic individuals

Study objectives
Comparison between ultrasound elastography and non-enhanced computed tomography Hounsfield units for diffuse fatty liver diseases in non-alcoholic individuals

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 26/11/2018, (Institutional ethical committee, Saveetha Medical College and Hospital, Thandalam - Tamil Nadu, India; +91 44-66726611; dir.res.su@gmail.com), ref: 602105.SMC/IEC /2018/11/234(A)

Primary study design
Observational

Study design
Single centre prospective observational study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Detection of fatty liver disease

Interventions
This prospective study included 137 samples in the age group of 10-80 years for a period of 12 months. This study was carried out at the Department of Radiology, Saveetha Medical College & Hospital, Saveetha university after approval from the Institutional Ethics Committee (November 26, 2018).
Patients were split into two groups based on diagnosis:
1. Disease group: non-alcoholic patients who have been referred by the physician to have NECT abdomen and diagnosed to have fatty liver
2. Control group: Other patients referred for NECT abdomen for any other reasons who don't have fatty changes in the liver

USG Elastography Study
All examinations were performed using an (AFFINITY, PHILIPS 70 USG scanner). All patients were first explained about the USG, the requirement of breath-hold during the measurement of liver stiffness values, and then written informed consent was obtained.
Protocol Examination included in 2D-SWE:
Probe used: Convex probe
Frequency range 1.5~6.0 MHz
Frequency: 3.0 MHz
Parameters Measured in 2D-SWE:
Liver stiffness measurements (LSM) of individual segments are taken from the upper left lobe (segment II), lower left lobe (segment III), and right lobe (segment V and VIII).
The mean liver stiffness measurement value (mean LSM) of the entire liver is derived by averaging the LSM values of all four segments.
Two similar-sized ROIs (~1 cm) are taken from each of the four segments, 2 cm beneath the liver capsule. This is repeated in the upper and lower poles of the spleen.
Care was taken to put the ROI at vessel-free liver and splenic parenchyma.

CT study
All examinations were performed using an (INGENUITY, PHILIPS 128 slice CT scanner), All patients were first explained about the CT, detailed clinical history was taken, previous medical records were checked, and then written informed consent was obtained.
Protocol Examination included:
Scan type: Helical

Patient orientation: Feet first
Acquisition: 5 mm
Reconstruction: 1 mm
Pitch factor: 1.6:1
Parameters measured in unenhanced CT:
Absolute HU of the liver (HU liver): Mean value of the absolute HU measurements taken from the upper left lobe (segment II), lower left lobe (segment III), and right lobe (segment V and VIII).
Absolute HU of the spleen (HU spleen): Mean value of the absolute HU measurements taken from upper and lower poles of the spleen.
Liver attenuation index (CTL-S): Difference in attenuation values between liver (HU liver) and spleen (HU spleen)
The grade of fatty liver disease as per the Five-point grading system. Two similar-sized ROIs (~1 cm) are taken from each of the four segments, 2 cm beneath the liver capsule. This is repeated in the upper and lower poles of the spleen.
Care was taken to put the ROI at vessel-free liver and splenic parenchyma.

Image analysis
In the USG 2D-SWE study, the liver stiffness measurement value (LSM value, measured by kPa) is calculated for each patient.
In non-enhanced CT, liver attenuation index value and the score of the visual five-point grading system are calculated.
At the end of both imaging investigations, we perform the following steps:
We compare the kPa value and liver attenuation index values to find whether there is a progressive rise in LSM value with increasing grade of steatosis or a progressive decrease in LSM value with increasing grade of steatosis.
We compare the kPa value with the score of the CT five-point grading system to find whether there is a progressive rise in LSM value with an increasing score of the CT five-point grading system or a progressive decrease in LSM value with an increasing score of CT five-point grading system.
Further, we calculate the sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of 2D-SWE when compared to the CT LAI grading system.

Statistical analysis
USG elastography kilo pascal values and CT Hounsfield unit were calculated. Comparison between various parameters was done using kappa agreement, Pearson's Chi-Square and Receiver Operating Characteristic curve, and p-value. Further, we calculate the sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of 2D-SWE compared to the CT LAI grading system.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ultrasound elastography, non-enhanced computed tomography

Primary outcome(s)
Measured at a single time point:
1. Quantitative assessment and Grading of fatty liver by Ultrasound Elastography

2. Quantitative assessment and Grading of fatty liver by Non-Enhanced Computed tomography based on Hounsfield units

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
30/11/2019

Eligibility

Key inclusion criteria
1. Disease group: non-alcoholic patients who have been referred by the physician to have NECT abdomen and diagnosed to have fatty liver
2. Control group: Other patients referred for NECT abdomen for any other reasons who don't have fatty changes in the liver
3. Age 11 - 80 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
137

Key exclusion criteria
1. Alcoholics with cirrhosis
2. Space-occupying lesions of the liver
3. Debilitated and ventilated patients
4. Pregnancy

Date of first enrolment
15/12/2018

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
India

Study participating centre
Saveetha medical college and hospital (SMCH)
Department of Radio-Diagnosis
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Sponsor information

Organisation
Saveetha University

ROR
https://ror.org/0034me914

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			04/05/2021	No	Yes