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Detecting chronic liver disease using transient elastography

Submission date
25/10/2015

Recruitment status
No longer recruiting

Registration date
15/12/2015

Overall study status
Completed

Last Edited
08/12/2015

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cirrhosis is a serious complication of liver disease, which involves widespread scarring of the liver. The damage to the liver caused by cirrhosis means that eventually the liver is unable to fulfil its normal functions, ultimately leading to liver failure. Often starting off with an accumulation of fat in the liver (fatty liver), cirrhosis develops gradually, however the damage to the liver is irreversible and gets worse over time. When cirrhosis is so advanced that the liver is unable to function, a liver transplant is the only treatment option. It has also been found that around 70% of people suffering from cirrhosis go on to develop hepatocellular carcinoma (the most common form of liver cancer). For this reason, it is very important to diagnose cirrhosis in its early stages, so that the patient has the best possible chance of survival. In order to examine the liver, a technique called ultrasound is used. 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 (FibroScan) 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. The aim of this study is to find out whether using transient elastography plus abdominal ultrasonography (TEAUS) is a more accurate way of detecting liver cirrhosis and fatty liver than using abdominal ultrasonography (AUS) alone.

Who can participate?
Healthy adults over 40 who have taken part in a multiple screening program in Changhua, Taiwan.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have their livers examined using TEAUS by an experienced operator. Those in the second group have their livers examined using AUS alone by an experienced technician. The number of participants who show signs of liver problems using each technique are then recorded and compared. If any liver disease is found, then participants in both groups are referred for a follow-up appointment so

that they can receive treatment. Between 5 and 10 years after this examination, participants in both groups are looked up on the national registry in order to find out how many have developed liver cancer or other serious liver disease, and how many in each group are still living.

What are the possible benefits and risks of participating?
Participants may benefit from earlier treatment if the TEAUS detects any liver disease. There are no risks of taking part in the study.

Where is the study run from?
South-West-North Districts Health Center (Taiwan)

When is the study starting and how long is it expected to run for?
January 2013 to February 2017

Who is funding the study?
Changhua County Public Health Bureau (Taiwan)

Who is the main contact?
Dr Tsung-Hui Hu

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
102-4647A3

Study information

Scientific Title
Community-based cluster randomized controlled trial using transient elastography in detecting chronic liver disease

Study objectives
Transient elastography plus abdominal ultrasonography (TEAUS) is more accurate at detecting liver cirrhosis and fatty liver than ultrasonography (AUS) alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Chang Gung Memorial Hospital, 23/01/2014, ref: 102-4647A3

Study design
Cluster randomized Ccontrolled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Liver disease

Interventions
The liver cancer screening conducted by participating health centres are randomly allocated to one of two groups:

Group 1: Abdomen screened using Transient elastography plus abdominal ultrasonography (TEAUS). This intervention involves the liver examinations by Transient elastography and abdominal ultrasonography simultaneously on the health centre. Both examinations are operated by different well-trained Gastroenterologists blindly and the finding reports are also separated to record. For those participants were diagnosed liver fibrosis or cirrhosis, they will refer to clinic for follow-up and care. The definitions of clinical referral are either the significant liver softness larger than 12 kPa by Transient elastography or liver cirrhosis image by abdominal ultrasonography.

Group 2: Abdomen screened using conventional abdominal ultrasonography (AUS) alone. This group involves the liver examination by abdominal ultrasonography only. For those who are diagnosed with liver cirrhosis which is defined as liver cirrhosis image, they will refer to clinic follow-up and care.

Referral and clinical care for both groups are same and pay by national health insurance.

The adding detection rates of liver fibrosis and softness is defined as secondary outcome for evaluation without follow-up because those results can collect from abdominal examination. The incidence and mortality rates of liver cancer or related liver diseases are evaluated as primary outcome of our study after 5-10 years follow-up.

Intervention Type
Device

Primary outcome measure
1. Incidence of HCC or related liver disease is determined using the Taiwanese Cancer Registry and National Mortality Registry at 5 and 10 years post scanning examination
2. Mortality rates are measured using the Taiwanese National Mortality Registry at 5 and 10 years post scan

Secondary outcome measures
Detection rates of liver fibrosis and softness using transient elastography plus abdominal ultrasonography compared with ultrasonography only following completion of the scanning examination.

Overall study start date
01/01/2013

Completion date
05/02/2017

Eligibility

Key inclusion criteria
1. Aged 40 and over
2. No severe chronic diseases
3. Have been invited and attended a multiple screening program in Changhua, Taiwan

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants

We plan to have 445 clusters and about 30 participants for each cluster due to sufficient time for TE and AUS diagnosis.

Key exclusion criteria
1. Those who have hepatocellular carcinoma (HCC) or other severe chronic diseases

Date of first enrolment
01/07/2013

Date of final enrolment
05/02/2017

Locations

Countries of recruitment
Taiwan

Study participating centre
South-West-North Districts Health Center
No.166, Xuguang Road
Changhua City
Taiwan
500

Sponsor information

Organisation
Changhua County Public Health Bureau

Sponsor details
No.162, Section 2, Jhongshan Road
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Sponsor type
Government

Website
http://www.chshb.gov.tw/en_sitemap/

ROR

https://ror.org/04t4g7j44

Funder(s)

Funder type
Government

Funder Name
Changhua County Public Health Bureau

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration