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Liver disease early detection study

Submission date
26/06/2014

Recruitment status
No longer recruiting

Registration date
06/08/2014

Overall study status
Completed

Last Edited
03/05/2017

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
Between 1970 and 2010, death rates from liver disease have increased five-fold in the UK, with the vast majority of deaths due to alcohol-related liver disease. It is difficult to detect the development of liver disease as patients tend not to have symptoms in the early stages. Although half of patients who eventually come into contact with liver specialist services will stop drinking, half of this group die before their livers are able to recover. One third of patients admitted to hospital with alcohol-related liver disease will die within a year from a complication of their illness. However, those who survive this period are likely to do well if they stop drinking. In the recent ALDDeS study, ,blood tests were taken for patients with a high alcohol intake to look for evidence of developing liver disease. It was found that about half of patients had a high or possible risk of liver disease, and these patients were shown to reduce their drinking up to a year after the tests. The study was based in GP surgeries and showed that it is possible to identify patients at risk of liver disease. In this study, a separate test to assess for liver disease (liver elastography) is tested. This is a simple, non-invasive test that involves measuring how stiff the liver is with a probe; there are no complications or side effects. The aim of this study is to see how accurate liver elastography is compared with the blood tests, and the possibility of using these tests in a GP practice.

Who can participate?
Patients identified in the ALDDeS study at high risk of liver disease will be invited to participate.

What does the study involve?
The study involves attending one mutually agreed, 30-minute appointment with a member of the study team at a GP practice. Participants complete a short alcohol questionnaire and answer some further questions about their alcohol consumption. They are then offered a repeat of the blood test that they had in the ALDDeS study, and have their liver assessed by elastography, which is similar to having an ultrasound scan of the liver. This procedure is painless and takes about 5-10 minutes. Participants receive a letter with their test results from the study team, which is copied to their GP.

What are the possible benefits and risks of participating?
The possible benefit is that participants suspected of having early liver disease can be alerted and referred for specialist consultation as necessary. The wider benefits include helping the study team see how useful each test is in helping identify those people who are silently

developing liver disease. There are no risks as such in participating, although sometimes it is not always possible to obtain an accurate elastography reading in some people.

Where is the study run from?
The study sites are eight GP surgeries in and around the Southampton area (UK) that were previously involved in the ALDDeS study:
1. Three Swans Surgery, Salisbury Wiltshire
2. Nightingale Surgery, Romsey, Hampshire
3. Brockenhurst Surgery, New Forest Medical Group, Hampshire
4. Wilton Health Centre, Salisbury, Wiltshire
5. Rosemary Medical Centre, Poole, Dorset
6. Endless Street Surgery, Salisbury, Wiltshire
7. Gosport Medical Centre, Gosport, Hampshire
8. Oakley and Overton Surgery, Overton, Hampshire

When is the study starting and how long is it expected to run for?
March 2014 to November 2014

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
16718

Study information

Scientific Title
Fibroscan elastography staging of liver disease in participants from the ALDDeS study

Study objectives
The principal question is to assess for the presence of liver fibrosis using liver elastography, in a community population already deemed high risk of liver disease using serum fibrosis markers (Southampton Traffic Light test), and to assess if there is any correlation between the two methods.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/SC/0002; First MREC approval date 14/01/2014

Study design
Non-randomised; Observational; Design type: Validation of investigational/therapeutic procedures

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Topic: Primary Care; Subtopic: Not Assigned; Disease: All Diseases

Interventions
The study involves attending one mutually agreed, 30-minute appointment with a member of the study team at a GP practice. Participants complete a short alcohol questionnaire and answer some further questions about their alcohol consumption. They are then offered a repeat of the blood test that they had in the ALDDeS study (Southampton Traffic Light Test, a panel of serum

fibrosis markers and platelet count blood test), and have their liver assessed by portable transient liver elastography (FibroScan). This procedure is painless and takes about 5-10 minutes. Participants receive a letter with their test results from the study team, which is copied to their GP.

Follow Up Length: 0 month(s); Study Entry: Registration only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Positive predictive value of Southampton Traffic Light Test; Timepoint(s): On assessment with liver elastography

Key secondary outcome(s))
Not provided at time of registration

Completion date
18/07/2015

Eligibility

Key inclusion criteria
Participants from the previous study ALDDES who were found to be at a possible or probable risk of liver fibrosis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Known pre-existing liver disease

Date of first enrolment
11/03/2014

Date of final enrolment
18/07/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Aldermoor Health Centre
Southampton
United Kingdom
SO16 5ST

Study participating centre
GP surgeries in Hampshire and Wiltshire
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Sponsor information

Organisation
University of Southampton (UK)

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research School for Primary Care Research (UK); Grant Codes: 241

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Planned dissemination of data in forthcoming publications related to ongoing work

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes