

Liver disease early detection study

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| Submission date 26/06/2014 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 06/08/2014 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 03/05/2017 | Condition category Digestive System | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Mrs Judy Chatwin

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Contact information

Type(s)

Scientific

Contact name

Mrs Judy Chatwin

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

11/03/2014

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

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 90; UK Sample Size: 90; Description: Participants from a previous study ALDDES who were assessed as a possible or probable risk of liver fibrosis

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**

England

United Kingdom

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)

Sponsor details

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Sponsor type

University/education

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

Publication and dissemination plan

Estimated date of publication is end 2017/early 2018.

Intention to publish date

31/12/2017

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 |