

Exercise and fatty liver with moderate alcohol consumption

Submission date 08/01/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/06/2017	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Non-alcoholic fatty liver disease (NAFLD) is a term used to describe a range of conditions caused by a build-up of fat within the liver. A normal liver should have no, or very little, fat. Simple fatty liver, which is harmless, is common in people who are overweight or obese. Over time, however, simple fatty liver can develop into non-alcoholic steatohepatitis (NASH) where the liver becomes inflamed. At this stage, people might experience a dull ache in their abdomen but it often has no symptoms. Persistent inflammation of the liver can develop into fibrosis where fibrous scar tissue develops around liver cells and blood vessels. The liver is still able to function normally at this stage. The final stages are cirrhosis and end-stage liver disease, in which the scarring is so extensive that the liver shrinks, becomes lumpy and begins not to function normally. Recent information has shown that exercise may help people with fatty liver. It may help reduce the amount of fat in the liver by increasing the ability of the body to burn fat and increasing the sensitivity of the body to food. Evidence also suggests that exercise may help to reduce active injury and inflammation in the liver. The aim of this study is to show the effect of exercise on the levels of fat, injury and inflammation in the liver and the sensitivity of the body to food. Understanding the relationship between exercise and liver injury is important in gaining acceptance of exercise in the management of fatty liver and avoiding excess weight gain.

Who can participate?

Adults aged between 18-75 with a fatty liver who drink a moderate amount of alcohol, do not do a lot of exercise and are at a stable weight

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) undergo 12 weeks of supervised exercise. Those in group 2 (control group) do not attend any exercise sessions. Both groups of participants go to the research facility 5 times throughout the 12-week exercise period, in which the amount of fat in the liver is measured using an MRI scan and blood tests are carried out to check for liver injury and inflammation.

What are the possible benefits and risks of participating?

Being more physically active may be beneficial to the level of fat, injury and inflammation in the liver and if sustained after the study, may help in preventing other complications such as heart

disease and diabetes. Participants in the intervention group have supervised exercise sessions (like a personal trainer) which will teach them about their body, show them how to exercise correctly and help them become more physically fit. Participants in the control group are given the opportunity to have an individualised exercise programme. There are minimal risks to taking part in the exercise programme.

Where is the study run from?

University of Newcastle upon Tyne (UK)

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

January 2014 to November 2014

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Ms Julia Maddison

Contact information

Type(s)

Scientific

Contact name

Ms Julia Maddison

Contact details

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United Kingdom
NE2 4HH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

14948

Study information

Scientific Title

The effect of exercise on liver lipid in people with fatty liver with moderate alcohol intake

Study objectives

To characterise the effects of resistance exercise upon factors which influence the development and progression of fatty liver in people who regularly consume a moderate amount of alcohol.

1. The primary aim is to observe whether performing a programme of resistance exercise reduces liver fat in people diagnosed with fatty liver in the absence of any changes in alcohol consumption.
2. The secondary aims are to understand the influence of resistance exercise upon factors which influence the development and progression of fatty liver to steatohepatitis: insulin sensitivity, lipid oxidation, regional adiposity, and cytokine production. In combination, these observations will provide the first report of resistance exercise upon fatty liver with continued alcohol intake and its underlying mechanisms. These novel observations will lay the foundation for a larger study to define the effectiveness of resistance exercise as a part of the clinical care of people with fatty liver who continue to drink alcohol.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Sunderland NRES committee, 06/03/2013, ref: 12/NE/0411

Study design

Non-randomised; Interventional

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Topic: Hepatology; Subtopic: Hepatology; Disease: All Hepatology

Interventions

Participants will undergo five metabolic assessment visits to the research facility, interspersed by either 12 weeks of supervised exercise therapy or continue their normal care.

Intervention Type

Other

Primary outcome measure

Liver lipids, abdominal fat content, insulin sensitivity, lipid oxidation and inflammation;
Timepoint(s): 12 weeks

Secondary outcome measures

N/A

Overall study start date

01/02/2014

Completion date

16/03/2015

Eligibility

Key inclusion criteria

1. Fatty liver
2. Moderate alcohol consumption (18-42 units/week for men; 11-28 units/week for women)
3. Sedentary
4. The person's weight needs to be stable prior to entering the study
5. Aged over 18
6. Understanding of English

Target Gender: Male & Female; Upper Age Limit 75 years; Lower Age Limit 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 28; UK Sample Size: 28

Key exclusion criteria

1. In vivo ferrous material preventing MRI examination
2. Glitazones (rosiglitazone and pioglitazone) are not permitted. All other insulin sensitising medication must be stable for previous 6 months
3. HBA1c >9.5
4. Current weight loss or change in drinking habits
5. Vitamin E (>400UI/day), PUFAs (>2g/day) and Ursodeoxycholic acid are not permitted
6. Currently taking drugs that can induce Steatosis/steatohepatitis: corticosteroids (parenteral administration only), amiodarone (Cordarone), Tamoxifen (Nolvadex), methotrexate (Rheumatrex, Trexall)

Date of first enrolment

01/03/2014

Date of final enrolment

01/03/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Newcastle upon Tyne

Newcastle upon Tyne

United Kingdom

NE2 4HH

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details

Leazes Wing, Royal Victoria Infirmary

Queen Victoria Road

Newcastle Upon Tyne

England

United Kingdom

NE1 4LP

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

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

Will be presented at liver conferences such as the European Association for the Study of Livers

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2017		Yes	No
HRA research summary			28/06/2023	No	No