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Exercise and fatty liver with moderate alcohol consumption

Submission date	Recruitment status	[_] Prospectively registered
08/01/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/01/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/06/2017	Nutritional, Metabolic, Endocrine	

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
University of Newcastle upon Tyne
Mitochondrial Research Group
Framlington Place
Newcastle upon Tyne
United Kingdom
NE2 4HH

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Non-randomised; Interventional

Study type(s)
Treatment

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

Key secondary outcome(s)
N/A

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

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

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

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