

Exercise and non-alcoholic steatohepatitis

Submission date 08/01/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol ☐ Statistical analysis plan ☒ Results ☐ Individual participant data
Registration date 09/01/2015	Overall study status Completed	
Last Edited 22/08/2016	Condition category Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims

Fatty liver disease 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. We want 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.

Who can participate?

Adults aged at least 18 with diagnosed NASH, who 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 a magnetic resonance scanner) and blood tests are taken 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 do a 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 2013 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

13894

Study information

Scientific Title

The effect of exercise on active liver injury, inflammation and liver lipid in people with non-alcoholic steatohepatitis

Study objectives

To characterise the effects of resistance exercise upon factors which influence the development and progression of non-alcoholic steatohepatitis (NASH).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Primary study design

Interventional

Study design

Randomised; Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Metabolic and endocrine disorders, Hepatology; Subtopic: Metabolic and Endocrine (all Subtopics), Hepatology; Disease: Metabolic & Endocrine (not diabetes), 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

Behavioural

Primary outcome(s)

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

Key secondary outcome(s)

N/A

Completion date

10/11/2014

Eligibility

Key inclusion criteria

1. NASH confirmed by liver biopsy; this is the study group
2. Sedentary; we are looking at the effect of increased exercise
3. The person's weight needs to be stable as we are interested in the independent effect of exercise
4. Aged 18 years and over
5. Understanding of English (as without this supervised gym visits will not be possible)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

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5. Understanding of English (as without this supervised gym visits will not be possible)

Date of first enrolment

01/03/2013

Date of final enrolment

01/03/2015

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

University of Newcastle upon Tyne

Mitochondrial Research Group

Framlington Place

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	01/01/2017		Yes	No
HRA research summary			28/06/2023	No	No