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Exercise and non-alcoholic steatohepatitis

Submission date
08/01/2015

Recruitment status
No longer recruiting

Registration date
09/01/2015

Overall study status
Completed

Last Edited
22/08/2016

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
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Framlington Place
Newcastle upon Tyne
United Kingdom
NE2 4HH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)
Sunderland NRES committee, 02/01/2013, ref: 13/NE/0041

Study design
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 the contact details below to request a patient information sheet

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

Secondary outcome measures
N/A

Overall study start date
01/03/2013

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 28; UK Sample Size: 28; Description: 14 participants per group to allow 3 people from each group to leave the study and retain sufficient power.

Key exclusion 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)

Date of first enrolment
01/03/2013

Date of final enrolment
01/03/2015

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor details
Midwifery Research Dept
Leazes Wing
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	01/01/2017		Yes	No
HRA research summary			28/06/2023	No	No