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Resistance exercise and non-alcoholic fatty liver disease

Submission date	Recruitment status	[_] Prospectively registered
23/04/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/07/2013	Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
6955; G0802536

Study information

Scientific Title

The effect of resistance exercise on metabolism and liver lipid in people with non-alcoholic fatty liver disease

Study objectives
The purpose of the study is to characterise the effects of resistance exercise upon factors which influence the development and progression of non-alcoholic fatty liver disease (NAFLD). The primary aim is to observe whether performing resistance exercise reduces liver lipid content in people with NAFLD. The secondary aims are to understand the influence of resistance exercise upon factors which influence the development of NAFLD: insulin sensitivity, lipid oxidation, regional adiposity and cytokine production.

Ethics approval required
Old ethics approval format

Ethics approval(s)
County Durham and Tees Valley 2 REC approved on the 28th September 2009 (ref: 09/H0908/48)

Study design
Non-randomised interventional prevention and treatment trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not available in web format, please contact kate.hallsworth@ncl.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Metabolic and Endocrine, Oral and Gastrointestinal; Subtopic: Metabolic and Endocrine (all Subtopics); Disease: Metabolic & Endocrine (not diabetes), Hepatology

Interventions
Participants will be assigned to the exercise or control group. The exercise group will undergo 8 weeks of resistance training 3 times per week. The intensity of the programme will be tailored to each individual and be increased progressively over the 8 weeks. The control group will continue with standard clinical care. Follow up length: 4 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
A quantitative measure of liver fat will be made using H magnetic resonance spectroscopy. Primary and secondary outcome measures will be made at baseline and after the 8 week exercise intervention/8 week control period.

Secondary outcome measures
1. Insulin sensitivity
2. Lipid oxidation
3. Cytokine production
4. Regional adiposity
5. Body composition

Primary and secondary outcome measures will be made at baseline and after the 8 week exercise intervention/8 week control period.

Overall study start date
01/08/2009

Completion date
01/06/2010

Eligibility

Key inclusion criteria
1. Diagnosed NAFLD or raised liver enzymes
2. Type 2 diabetes (diet or metformin controlled)
3. Body mass index (BMI) between 25 - 35 kg/m^2
4. Aged 18 - 70 years
5. Subjects should not already take part in regular exercise

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. Subjects with kidney disease or in vivo ferrous metal
2. Subjects that have other pre-existing medical conditions which could prevent them from exercising 3 x per week

3. Subjects with type 2 diabetes on insulin or insulin sensitising treatments
4. Subjects with advanced liver disease

Date of first enrolment
01/08/2009

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Westgate Road
Newcastle Upon Tyne
United Kingdom
NE4 6BE

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Midwifery Research Dept
Leazes Wing
Queen Victoria Road
Newcastle upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Research council

Funder Name
Diabetes UK (UK)

Alternative Name(s)
DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Medical Research Council (MRC) (UK) (ref: G0802536)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

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	01/09/2011		Yes	No