ISRCTN95105191 https://doi.org/10.1186/ISRCTN95105191

The effects of exercise on pathophysiology of chronic diseases related to obesity

Submission date
16/07/2013

Recruitment status
No longer recruiting

Registration date
24/07/2013

Overall study status
Completed

Last Edited
24/07/2013

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Lifestyle change, including change in diet and physical activity, is essential for the treatment of obesity and type 2 diabetes. Regular exercise is also one of the best preventive methods against chronic diseases that are not related to obesity. Skeletal muscles produce substances called myokines. Myokines could play an important role in the prevention of chronic diseases associated with obesity, prediabetes and type 2 diabetes. Discovering new myokines and improving our understanding of how they act might provide new targets for treatment of metabolic and cardiovascular diseases, and might help to explain the different effects of aerobic and strength training on obesity, metabolic health and physical fitness.
In this study we will investigate the effects of aerobic and strength training on myokines produced in skeletal muscle and in the muscle cells originating from obese prediabetic individuals (people with glucose levels that are higher than normal but not high enough yet to indicate diabetes). We will also study the effects of aerobic and strength training on metabolic phenotypes (metabolites in the body that accurately reflect an individuals health status) and body composition.

Who can participate?
Men and women 30-45 years of age with a body mass index of 30-35 kg/m2, preferably with reduced glucose tolerance or increased fasting blood glucose level without treatment.

What does the study involve?
The following examinations will be performed before and after a 3-month training program:
1. Blood sampling
2. Skeletal muscle biopsy
3. Assessment of body composition
4. Monitoring of daily physical activity
5. Questionnaires to determine the physical activity, food preference, and personal and family history of the volunteer

What are the possible benefits and risks of participating?
The benefits include an early detection of metabolic disorder with a possible early treatment. The greatest benefit is represented by exercise training with a potential to improve the

metabolic phenotype and body composition of volunteers. The exercise training is supplemented by motivational lectures with the aim to educate them on the importance and impact of an active lifestyle.
The risks of the study are minor, since the pre-entry health examinations and all the procedures included in the study protocol are performed by experienced doctors in the appropriate clinical setting and exercise training is individually tailored and supervised by professional trainers. The blood sampling is associated with a small risk of bruise and inflammation of the veins. The muscle sampling might very rarely cause a reduced sensitivity in a small region of skin in the thigh (with spontaneous recovery) or severe bruising. Vigorous exercise can result in injuries. In our study we minimize this risk by tailoring exercise to the volunteers individual needs, based on the assessment of his or her physical fitness and muscular strength, with gradual increases in the work-load as well as by implementing the supervised exercise training program.

Where is the study run from?
Institute of Experimental Endocrinology, Slovak Academy of Sciences (Slovakia)

When is the study starting and how long is it expected to run for?
The study started in March 2011 and will run until July 2013.

Who is funding the study?
The study is funded by The European Federation for the Study of Diabetes and Lilly Research Fellowship Program.

Who is the main contact?
Barbara Ukropcová, MD, PhD
barbara.ukropcova@savba.sk

Contact information

Type(s)
Scientific

Contact name
Dr Barbara Ukropcova

Contact details
Obesity Section of Diabetes Laboratory
Institute of Experimental Endocrinology SAS
Vlarska 3
Bratislava
Slovakia
833 06
barbara.ukropcova@savba.sk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effects of exercise on the pathophysiology of chronic diseases related to obesity: the role of myokines and microRNAs

Study objectives
Our hypothesis is that exercise training will
1. Improve the whole body metabolic phenotype and physical fitness even without significant weight loss
2. Specifically modulate the expression of genes and proteins related to adaptive changes in muscle produced cytokine spectrum, as well as the secretory profile of primary skeletal muscle cells
3. Change the epigenetic characteristics by specifically modulating the miRNAs expressed in response to exercise.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study was approved by the Ethics Committee of the University Hospital Bratislava, Comenius University Bratislava

Study design
3-months exercise intervention study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Obesity, prediabetes

Interventions

One hour lasting training sessions, preceded by 10 min warm up and followed by cool down - stretching exercises, are to be held 3 times per week. Sessions of aerobic dance, running and spinning with exercise professionals is provided. Intensity of aerobic exercises is monitored and evaluated by Polar RS300X (Polar, Finland) during each session. Intensity will be maintained at 70-85% of maximal heart rate. Strength training will be aimed at improving the performance of the major muscle groups. After initial strength testing with the computer-controlled dynamometer (horizontal leg-press developed at the FPES CU, Bratislava, Slovakia), training is initiated by using 50-60% of the 1 repetition maximum (1RM). Load will progressively be increased in the course of the training study according to the individual initial performance level. Adherence to the training program will be closely monitored and regularly encouraged.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Specific molecular changes in spectrum of muscle secreted products (proteins & miRNA) with acute bout of exercise and with the exercise training

Secondary outcome measures
1. Maximal aerobic capacity (VO2max) will be calculated from the continuous measurement of the gas exchange (Ergostik, Geratherm Respiratory, Bad Kissingen, Germany) during an incremental exercise test (Lode-Corival cycle ergometer, Lode B.V., Groningen, The Netherlands) and expressed relative to lean body mass.
2. Lean body mass
3. Body weight and height will be used to calculate BMI (kg.m-2).
4. Waist circumference will be measured at the midpoint between the lower border of the rib cage and the iliac crest.
5. Bioelectric impedance will be used to evaluate total and visceral adiposity and to estimate lean body mass (Omron BF511, Omron Healthcare LTD., Matsusaka, Japan).
6. Resting energy expenditure will be measured after an overnight fast and following 30min bed rest with the Ergostik (Geratherm Respiratory, Bad Kissingen, Germany) for a period of 30 minutes.
7. Volume and dynamics/intensity of daily ambulatory activity will be determined with accelerometers (Lifecorder plus, Kenz, USA) used continually within the 3-month exercise intervention period.
8. Abdominal fat distribution will be measured in all individuals (both studies) by MRI (1.5 T Magnetom Symphony MRI scanner, Siemens, Germany).
9. Imaging of the calf muscle will enable exact calculation of muscle volume and spectra from tibialis anterior (postural oxidative) muscle acquired by using 1H-MR spectroscopy, used to asses content of intra- and extramyocellular lipids.
10. Hepatic lipid content will be determined by similar 1H MRS technique (as described above).
11. Resting-state muscle ATP turnover with 31P-MRS (magnetization transfer experiment)
12. Level of glucose intolerance using oral glucose tolerance test
13. Fasting plasma glucose, insulin, total and HDL cholesterol, triglycerides and free fatty acids

Overall study start date
31/03/2011

Completion date
30/07/2013

Eligibility

Key inclusion criteria
1. Men and women 30-40 years of age
2. Signed written informed consent
3. Volunteers with BMI 30-35 kg/m2 fulfilling the criteria of impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) without pharmacotherapy
4. Lean healthy volunteers (the effect of acute exercise bout)

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Acute infectious disease
2. Chronic systemic diseases (cardiovascular disease, chronic diseases of liver and kidneys, diabetes mellitus, oncologic disease or other serious disease, based on the assessment of the responsible physician and investigator)
3. Non-compliance of the volunteer

Date of first enrolment
31/03/2011

Date of final enrolment
30/07/2013

Locations

Countries of recruitment
Slovakia

Study participating centre
Obesity Section of Diabetes Laboratory
Bratislava
Slovakia
833 06

Sponsor information

Organisation
Institute of Experimental Endocrinology Slovak Academy of Sciences (Slovakia)

Sponsor details
c/o Barbara Ukropcova, MD, PhD
Obesity Section of Diabetes Laboratory
Vlarska 3
Bratislava
Slovakia
833 06
barbara.ukropcova@savba.sk

Sponsor type
Research organisation

ROR
https://ror.org/01a1nz002

Funder(s)

Funder type
Research organisation

Funder Name
Foundation for the Study of Diabetes & Lilly research fellowship programme (EFSD Germany & Lilly USA)

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