Effects of acute elevation of circulating fatty acids on skeletal muscle lipid accumulation in healthy lean young men

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38652

Source
ToetsingOnline

Brief title
Elevated FFA and skeletal muscle lipid content

Condition

- Other condition

Synonym
Skeletal muscle metabolism, The metabolic process of the skeletal muscle

Health condition

Skeletal muscle lipid metabolism

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: 2e Geldstroom (ZonMw via UM)

Intervention

Keyword: Exercise, Intramuscular lipid content

Outcome measures

Primary outcome

Skeletal muscle lipid content before, directly after exercise and 4 h post

exercise (determined from muscle biopsies) with or without glucose

supplementation.

Secondary outcome

not applicable

Study description

Background summary

There is increasing evidence that skeletal muscle lipid content (IntraMyoCellular Lipid, IMCL) markedly increases the risk of metabolic complications, including insulin resistance and cardiovascular events. We hypothesize that skeletal muscle is passively taking up FFAs when the availability is high, thereby leading to an increased storage. To test this hypothesis, we want to manipulate FFA levels, by means of exercise, and monitor intramuscular lipid content.
Objective: To examine the effect of an exercise-induced elevation of FFA on skeletal muscle lipid content. To this end, we compare skeletal muscle lipid content at baseline and after an exercise protocol and again after a four-hour recovery period from exercise, once in a condition with high FFA concentration, once with low FFA concentration. To achieve high- versus low FFA concentrations, we chose a protocol with cycling exercise either with- or without glucose supplementation.
Study design: Skeletal muscle lipid content will be determined in a condition with high plasma FFA (cycling and recovery in fasted state) and in a low FFA condition (cycling and recovery with glucose supplementation). Remaining fasted

during cycling and recovery has been shown to result in strongly increased FFA levels, while glucose supplementation completely blunts the increase in FFA. To determine the effect of acute exercise, skeletal muscle lipid content will be measured before and after cycling.
Study population: In this study 20 healthy lean young men (18-30 years, BMI 18-25 kg/m2) will be recruited.
Intervention (if applicable): Subjects will perform a two-hour cycling test, once fasted (high FFA condition) and once with glucose supplementation (low FFA condition). To determine the effect of high versus low FFA concentration, skeletal muscle lipid content will be determined in both conditions at baseline and 4 hours after recovery from exercise. To determine the effect of acute exercise, skeletal muscle lipid content will be compared before and after the cycling exercise.
Main study parameters/endpoints: Skeletal muscle lipid content before, directly after exercise and 4 h post exercise (determined from muscle biopsies) with or without glucose supplementation.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Subjects will come to the university three times. First the subjects will be screened to access eligibility, which will include filling in a medical history questionnaire, and a measurement of height and body weight. Body composition will also be accurately determined by hydrostatic weighing and the subjects* maximal aerobic capacity will be determined by an exercise test. In total this will take approximately 2 hours. The second and the third visit are test days (ca. 8 h), for which subjects have to report to the university in the morning in the fasted state. During these test days subjects will undergo three muscle biopsies (before, directly after exercise and again 4 h post exercise) and exercise for a total duration of 2 hours.
No direct health benefit for the participants is expected. The experimental procedures are without risks, except for blood sampling and sampling of muscle biopsies, which can occasionally cause a local haematoma or bruise and the maximal test and cycling protocol can cause muscle soreness. Measurements performed during the time course of the study can potentially lead to coincidental medical findings. Subjects will be informed about such a finding and possible advised to contact a doctor about this.

Study objective

To examine the effect of an exercise-induced elevation of FFA on skeletal muscle lipid content. To this end, we compare skeletal muscle lipid content at baseline and after an exercise protocol and again after a four-hour recovery period from exercise, once in a condition with high FFA concentration, once with low FFA concentration. To achieve high- versus low FFA concentrations, we chose a protocol with cycling exercise either with- or without glucose supplementation.

Study design

Skeletal muscle lipid content will be determined in a condition with high plasma FFA (cycling and recovery in fasted state) and in a low FFA condition (cycling and recovery with glucose supplementation). Remaining fasted during cycling and recovery has been shown to result in strongly increased FFA levels, while glucose supplementation completely blunts the increase in FFA. To determine the effect of acute exercise, skeletal muscle lipid content will be measured before and after cycling.

Intervention

Subjects will perform a two-hour cycling test, once fasted (high FFA condition) and once with glucose supplementation (low FFA condition). To determine the effect of high versus low FFA concentration, skeletal muscle lipid content will be determined in both conditions at baseline and 4 hours after recovery from exercise. To determine the effect of acute exercise, skeletal muscle lipid content will be compared before and after the cycling exercise.

Study burden and risks

Subjects will come to the university three times. During the first visit subjects height and body weight will be measured. Body composition will also be accurately determined by hydrostatic weighing and the subjects* maximal aerobic capacity will be determined by an exercise test. In total this will take approximately 2 hours.
The second and the third visit are test days (ca. 8 h), for which subjects have to report to the university in the morning in the fasted state. During these test days subjects will undergo three muscle biopsies (before, directly after exercise and again 4 h post exercise) and exercise for a total duration of 2 hours.
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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Male sex
- Age 18-30 years
- Lean, BMI 18-25 kg/m2
- Healthy
- Stable dietary habits
- No medication use

Exclusion criteria

- Female sex
- Engagement in programmed exercise > 2 hours total per week
- Cardiac problems, such as angina pectoris, cardiac infarction and arrhythmias
- First degree relatives with type 2 diabetes mellitus
- Any medical condition requiring treatment and/or medication use
- Unstable body weight (weight gain or loss > 3 kg in the past three months)
- Participation in another biomedical study within 1 month prior to the screening visit
- Subjects, who do not want to be informed about unexpected medical findings, or do not

wish that their treating physician is informed, cannot participate in the study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-05-2013
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	28-03-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL43302.068.13
Other	www.clinicaltrials.gov