ISRCTN43780395 https://doi.org/10.1186/ISRCTN43780395

Effect of 12 weeks training on muscular lipid handling in relation to type 2 diabetes mellitus

Submission date
06/07/2009

Recruitment status
No longer recruiting

Registration date
28/08/2009

Overall study status
Completed

Last Edited
23/10/2020

Condition category
Nutritional, Metabolic, Endocrine

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

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
MEC06-3-038.5/pl

Study information

Scientific Title
Effect of 12 weeks training on muscular lipid handling in relation to type 2 diabetes mellitus: a single centre randomised controlled trial

Study objectives
Training improves insulin sensitivity via an increase in fat oxidative capacity of muscle, thereby reducing the accumulation of fatty acid metabolites like diacylglycerol (DAG).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Medical Ethics Committee (Medisch Ethische Commissie academisch ziekenhuis Maastricht /Universiteit Maastricht [MEC azM/UM]) approved on the 12th June 2009 (ref: MEC06-3-038.5/pl)

Study design
Single centre interventional randomised controlled trial

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
Diabetes

Interventions
All subjects were engaged in an exercise program for 12 weeks consisting of a combination of aerobic and resistance exercise. The aerobic exercise was carried out twice a week for 30 minutes at 70% of their maximum aerobic capacity. Resistance exercise was performed once a week and consisted of three series of 10 repetitions at 60% of their pre-training maximum voluntary contraction (MVC). The mode of aerobic and resistance activity involved cycling exercise and a "circuit" of eight exercises concentrating on large muscle groups respectively. Each 4 weeks, maximal aerobic capacity and MVC was re-assessed, and the exercise intensity was adjusted. Skilled trainers supervised the exercise sessions to ensure compliance and to reduce the risk of injuries.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
insulin sensitivity (hyperinsulinaemic-euglycaemic clamp). All measurements are done at baseline and repeated after the 12-week training period.

Secondary outcome measures
All measurements are done at baseline and repeated after the 12-week training period:
1. Proteins involved in lipid handling
2. Lipid metabolites in skeletal muscle
3. Skeletal muscle oxidative capacity (muscle biopsies, aerobic exercise test)
4. Lipid accumulation in heart muscle and skeletal muscle (MRS)
5. Body composition
6. Mitochondrial markers and peripheral lipid accumulation in muscle (muscle biopsies)
7. Expression of proteins involved in fatty acid handling
8. Insulin signalling in skeletal muscle (muscle biopsies)

Overall study start date
12/06/2006

Completion date
18/07/2008

Eligibility

Key inclusion criteria
All subjects:
1. Male sex
2. Aged 50 - 65 years
3. Body mass index (BMI) 27 - 35 kg/m^2
4. Stable dietary habits and physical activity levels

For diabetic patients only:
5. Must be on sulphonylurea or metformin therapy for at least six months with a constant dose for at least two months, or on dietary treatment for at least six months
6. Well-controlled diabetes: fasting plasma glucose concentration must be less than 10.0 mmol/l at the time of screening

For healthy controls only:
7. Normoglycaemic according to World Health Organization (WHO) criteria (oral glucose tolerance test [OGTT])

Participant type(s)
Patient

Age group
Adult

Sex

Male

Target number of participants
18 diabetic subjects, 20 healthy control subjects

Total final enrolment
11

Key exclusion criteria
All subjects:
1. Female sex
2. Unstable body weight (weight gain or loss greater than 3 kg in the past three months)
3. Participation in an intensive weight-loss program or vigorous exercise program during the last year before the start of the study
4. Active cardiovascular disease. This will be determined by performing an exercise electrocardiogram (ECG), by questionnaires and by screening on medication. Furthermore, all subjects will undergo a physical examination by a medical doctor.
5. Liver disease or liver dysfunction (alanine aminotransferase [ALAT] greater than 2.5 x increased)
6. Renal dysfunction (creatinine greater than 2 x increased)
7. Systolic blood pressure greater than 160 mmHg or diastolic blood pressure greater than 100 mmHg
8. Haemoglobin less than 7.5 mmol/l (anaemia)
9. Use of medications know to interfere with glucose homeostasis (i.e. corticosteroids)
10. Use of anti-thrombotic medication
11. Claustrophobia and metal implants (with respect to magnetic resonance imaging [MRI])
12. Abuse of drugs and/or alcohol
13. Participation in another biomedical study within 1 month before the first screening visit

For diabetic subjects:
14. Severe diabetes which requires application of insulin or patients with diabetes-related complications

Date of first enrolment
12/06/2006

Date of final enrolment
18/07/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Universiteitssingel 50
Maastricht
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Sponsor information

Organisation
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.zonmw.nl

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Scientific Research (NWO) (Netherlands) - VIDI Research Grant for Innovative Research (ref: 917.66.359)

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	26/05/2011	23/10/2020	Yes	No