

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

☐ Prospectively registered

☐ Protocol

Registration date
28/08/2009

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
23/10/2020

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Matthijs Hesselink

Contact details
Universiteitssingel 50
Maastricht
Netherlands
6200MD
+31 (0)43 388 1317
matthijs.hesselink@bw.unimaas.nl

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

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/m²
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

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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 known 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

Netherlands

6200MD

Sponsor information

Organisation

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

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes