

The effect of a structured exercise program on oxidative capacity and mitochondrial (dys) function in type 2 diabetes

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Registration date 16/03/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/03/2010	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
P04.1659L (Dutch CCMO registration number)

Study information

Scientific Title

A study on the training response of combined strength and endurance training in insulin dependent type 2 diabetic subjects with co-morbidity

Study objectives

Exercise (partly) reverses mitochondrial dysfunction in patients with long-term type 2 diabetes and co-morbidity.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Medical Ethics Committee of the Maxima Medical Centre approved of the primary exercise intervention study on the 27th December 2004 (CCMO-registrationnumber P04.1659L). Subsequent amendment requests for extension of the study (including P06.0005L) were also approved.
2. Central Committee on Research inv. Human Subjects (CCMO) approved of the primary intervention study on the 21st December 2004 (CCMO-registration number: P04.1659)

Study design

Single centre longitudinal intervention case-control study with mixed design

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Type 2 diabetes

Interventions

Group A: usual care combined with a structured exercise intervention (3 times/week) for 12 months consisting of progressive resistance type of exercise combined with high-intensity interval type of endurance exercise.

Groups B and C served as control groups to enable a baseline comparison.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Change in phosphocreatine recovery time constant (τ_{PCr}) as a measure of in-vivo muscle oxidative capacity as measured using ^{31}P NMR spectroscopy, measured at $t = 22$ weeks and $t = 52$ weeks following the beginning of the exercise intervention.

Key secondary outcome(s))

1. Ex vivo mitochondrial density, quality and functioning in skeletal muscle (as measured through determining mitochondrial density (citrate synthase, mtDNA copy number) and ex vivo function and expression of Krebs cycle and OXPHOS related genes (measured at t = 11, 22 and 52 weeks following the beginning of the exercise intervention)
2. Change in maximal oxygen uptake capacity as measured on a bicycle ergometer (measured at t = 11, 22 and 52 weeks following the beginning of the exercise intervention)
3. Change in submaximal oxygen uptake and heart rate (at 50% Wmax) on a bicycle ergometer (measured at t = 11, 22 and 52 weeks following the beginning of the exercise intervention)
4. Change in HbA1c and exogenous insulin use (measured at t = 11, 22 and 52 weeks following the beginning of the exercise intervention)
5. Change in markers for chronic inflammation (high sensitivity C-reactive protein [hsCRP], tumour necrotising factor [TNF]-alpha) and adipokines (adiponectin) (measured at t = 11, 22 and 52 weeks following the beginning of the exercise intervention)
6. Change in body composition (as measured with dual energy X-ray absorptiometry [DEXA] /magnetic resonance imaging [MRI], waist circumference) (measured at t = 11, 22 and 52 weeks following the beginning of the exercise intervention)
7. Change in muscle strength of upper and lower extremities (measured at t = 11, 22 and 52 weeks following the beginning of the exercise intervention)
8. Change in quality of life (36-item short form [SF-36]) (measured at t = 22 and 52 weeks following the beginning of the exercise intervention)
9. Change in activity level (Tecumseh questionnaire) (measured at t = 22 and 52 weeks following the beginning of the exercise intervention)

Completion date

31/12/2008

Eligibility

Key inclusion criteria

Group A: long-term type 2 diabetes group (intervention group):

1. Male
2. Diagnosed with type 2 diabetes greater than 5 years according to World Health Organization (WHO) criteria
3. Exogenous insulin use greater than 2 years
4. Clinical signs of diabetic polyneuropathy and/or other diabetes-related
5. Aged 45 - 70 years
6. Body mass index (BMI) 26 - 42 kg/m²
7. Sedentary behaviour
8. Agreement to volunteer for the study by giving a written informed consent

Group B: intermediate hyperglycaemia group/early-diagnosed type 2 diabetes patients:

1. Male
2. Intermediate hyperglycemia according to WHO criteria
3. HbA1c less than or equal to 6.0%
4. Aged 45 - 70 years (matched with group A)
5. BMI 26 - 42 kg/m² (matched with group A)
6. Wmax (cycle ergometer): 100 - 220 Watt
7. Sedentary behaviour
8. Agreement to volunteer for the study by giving a written informed consent

Group C: overweight/obese but otherwise healthy subjects with normal glucose tolerance:

1. Male
2. Normal glucose tolerance according to WHO criteria
3. HbA1c less than or equal to 6.0%
4. Aged 45 - 70 years
5. BMI 26 - 42 kg/m² (matched with group A)
6. Wmax: 100 - 220 Watt
7. Sedentary behaviour
8. Agreement to volunteer for the study by giving a written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

Group A:

1. Unable to participate in a structured exercise intervention for 12 months
2. Use of thiazolidinions
3. Use of beta-blocker therapy less than 6 months

Group B and C:

1. Family history of type 2 diabetes
2. Use of beta-blocker therapy
3. History/clinical signs of cardiovascular and/or peripheral arterial disease

Date of first enrolment

01/01/2005

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus University Medical Centre

Rotterdam

Netherlands

3000 CE

Sponsor information

Organisation

University Maastricht (UM) (Netherlands)

ROR

<https://ror.org/02jz4aj89>

Funder(s)

Funder type

Government

Funder Name

Ministry of Health, Welfare and Sport (VWS) (Netherlands) - unrestricted research grant

Funder Name

Eindhoven University of Technology (Netherlands) - Department of Biomedical NMR

Funder Name

Dutch Diabetes Research Foundation (Netherlands) (ref: 2004.00.040)

Alternative Name(s)

Dutch Diabetes Research Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration