ISRCTN23677189 https://doi.org/10.1186/ISRCTN23677189

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

Submission date	Recruitment status	[ ] Prospectively registered
08/01/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/03/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/03/2010	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Stephan Praet

Contact details
Erasmus University Medical Centre
Office H-021
's Gravendijkwal 230
Rotterdam
Netherlands
3000 CE
s.praet@erasmusmc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Case-control study

Study setting(s)
Hospital

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 (Dutch only)

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 measure
Change in phosphocreatine recovery time constant (τPCr) 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.

Secondary outcome measures
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 oyxgen 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 (adoponectin) (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)

Overall study start date
01/01/2005

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/m^2
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/m^2 (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/m^2 (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

Age group
Adult

Sex
Male

Target number of participants
Group A: 12; group B: 12; group C: 12

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)

Sponsor details
Department of Human Movement Sciences
Universiteitssingel 50
Maastricht
Netherlands
6229 ER

Sponsor type
University/education

Website
http://www.unimaas.nl

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

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