Validating the SteepRamp test for estimating the physical fitness and an AGE test to predict tendinopathy structure in diabetes.

Published: 10-05-2010
Last updated: 01-05-2024

Substudy A• Validating the supramaximal SteepRamp exercise test to determine physical fitness in type 2 diabetes patients by correlating the result with a conventional VO2max exercise test and determining the test-retest reliability.Substudy B•…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON38192

Source
ToetsingOnline

Brief title
SteepRamp validation & tendon structure in DM

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Tendon, ligament and cartilage disorders

Synonym
Diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: NISB;Nederlands Instituut voor Sport en Beweging;Diabetes Fonds

Intervention

Keyword: Diabetes, Exercise test, SteepRamp, Tendon

Outcome measures

Primary outcome

Substudy A

• The VO2max measured during a maximal RAMP exercise test.

• The maximal workload in watts during a supra-maximal SteepRamp exercise test.

Substudy B

• Result of the UTC measurement.

Secondary outcome

Substudy A

• Workload in watts during maximal RAMP exercise test.

• Performance on an sub-maximal exercise test (0,5-1-1,5 watt/kg.2 min).

• Fat percentage, B.M.I. abdominal circumference.

• Isokinetic quadriceps strength.

• Time to complete a standardized Sit-to-Stand test.

• Estimated kcal expenditure over 7 days based on measurements using a

validated multi-sensor accelerometer (Actigraph®).

• Hemoglobin, HbA1c, plasma glucose, HDL-C, LDL-C, Total-Cholesterol,

triglycerides and free fatty acids (blood) and

microalbuminuria (urine).

Substudy B

• Result of the skin auto-fluorescence test using the AGE-reader®.

Study description

Background summary

Physical exercise has a prominent role in the treatment of type 2 diabetes mellitus (DM2). This research project aims to improve exercise intervention programs in DM2 by validating a novel easy applicable exercise test for determining physical fitness (substudy A) and investigating if advanced glycation endproducts (AGE) in the skin can predict tendon structure abnormalities that predispose tendinopathy (substudy B).

Substudy A
To improve the result and adherence of an exercise intervention in DM2 a individual tailored program is advised. Until now only a elaborative and expensive spiro-ergometry is available to optimize a exercise program for the individual patient. A short supra-maximal exercise test (SteepRamp-test, 25 Watt/10 sec) is used in post-chemotherapy patients and shows accurate correlation with VO2max measured with spiro-ergometry. The SteepRamp test has been proven safe in heart failure patients. Hence it can be suggested that the SteepRamp-test is accurate and effective in estimating physical fitness in DM2 patients. The study targets to validate the SteepRamp exercise test for estimating the VO2max in DM2 patients. The secondary objective is to correlate these data to results from a sub-maximal exercise test (0,5-1-1,5 watt/kg.2 min), an activity monitor and an isokinetic quadriceps strength test. The secondary goal aims to investigate the SteepRamp test as a measure to estimate daily activity pattern and muscle strength and to determine reference values for the DM2 population. To achieve the studies objective 135 DM2 patients (age 30-80 yr, BMI 27-40 kgm/2) will be included and undergo a spiro-ergometry, a SteepRamp and the sub-maximal exercise test on separate days. Furthermore the subjects will wear an activity monitor for 7 days and perform an isokinetic strength test.

Substudy B
The prevalence of tendinomuscular overuse injuries is one of the main reasons of premature termination of the exercise program in DM2. Chronic inactivity is considered an important cause of musculotendinous deconditioning and subsequent

injuries. However, advanced glycation endproducts (AGE) of collagen in the skin is a known manifestation of both type 1 and type 2 diabetes and can easily be determined using a skin autofluorescence test. This research hypothesizes that the glycation of collagen will also occur in the musculotendinous tissue predisposing tendinopathy in both type 1 and type 2 diabetes patiënts. Skin autofluorescence will be correlated with tendinopathy score based on a novel ultrasonic tissue characterization (UTC) technique. To test the hypothesis a group of 30 type 1 (aged 18-30 yr), and 30 type 2 (aged 35-60) diabetes patients of substudy A, will be requested to undergo a skin autofluorescence and UTC test. This group will be compared with a control group, matched for age, body composition, activity level and gender. A foot pressure measurement will be used to rule out biomechanical factors for tendinopathy of the Achilles tendon. When the hypothesis can be confirmed, the results will guide new research on tendomuscular overuse injuries and tailor-made prevention programs for diabetes patients.

Study objective

Substudy A
• Validating the supramaximal SteepRamp exercise test to determine physical fitness in type 2 diabetes patients by correlating the result with a conventional VO2max exercise test and determining the test-retest reliability.

Substudy B
• Comparing Achilles tendinosis incidence in diabetes patients with the incidence in matched controls.

Study design

Substudy A
- Cross-sectional observational validation study, intra-subject controlled

Substudy B
- Observational case vs. matched control study

Study burden and risks

Substudy A
•Maximal exercise test on a bicycle using spiroergometry, ECG and non-invasive blood pressure monitoring.
•Two times a 6 min. submaximal exercise test using the Åstrand protocol and a short (approx. 1-2 min.) supramaximal SteepRamp-
test, performed with a 20-30 min intermediate pause. These tests will be executed 7-10 days separated from the maximal exercise test.
• Registration of the daily physical activity during 7 days and carrying a validated multi-sensor accelerometer (Actigraph*).

• Isokinetic strength measurement (Biodex*, 5 rep's, 60 gr/s) of the quadriceps.
• Standardized Sit-to-Stand test (getting up form a chair in a standardized way).
• Weight and length measurement.
• Fat percentage estimation based on skin fold measurements.
• Waist circumference measurement.
• Blood sample obtained once from venous punction and urine test.
Testing will be performed on 5 separate days with an intermediate period of 7-10 days in 2-3 weeks.

There is a small risk of cardiac ischemia/arritmia or a hypoglycemic event during the exercise test. To reduce the risk of cardiac ischemia/arritmia all exercise test will be executed in a hospital setting with ECG monitoring and direct supervision of a physician. The risk of a hypoglycemic event is low considering the exercise tests are short. If necessary carbohydrate solutions or, in case of loss of consciousness, Glucagon (Glycagen®, 1 mg dissolved in 1 ml) are available.

Substudy B
• Weight and length measurement.
• Fat percentage estimation based on skin fold measurements.
• Waist circumference measurement.
• Forearm skin auto-fluorescence measurement using AGE-reader®
• UTC measurement of the Achilles tendon
• Foot pressure measurement
• Blood sample obtained once from venous punction and urine test.
• Registration of the daily physical activity during 7 days and carrying a validated multi-sensor accelerometer (Actigraph*).

No associated risks

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

Substudy A
• Type 2 diabetes mellitus
• Age: 30-80 years
• Formal permission to participate in the study by signing an informed consent form
Substudy B
30 cases from substudy A will be included in substudy B
• Type 2 diabetes mellitus
• Age: 35-60 years, (15 male, 15 female)
• Formal permission to participate in the study by signing an informed consent form
30 type 1 diabetes patients
• Type 1 diabetes mellitus
• Age: 18-30 years, (15 male, 15 female)
• Formal permission to participate in the study by signing an informed consent form
60 controls will be matched for gender and age

Exclusion criteria

Substudy A and B
• Cardiovascular disease: objectived heart failure (ejection fraction <35%), electrocardiographically objectived cardiac ischemia or symptomatical peripheral vascular disease objectived by Doppler ultrasound investigation
• Serious orthopedic of neurological conditions precluding an exercise test or muscle strength test;Substudy B

• Use of fluoroquinolones

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-05-2010
Enrollment:	225
Type:	Actual

Ethics review

Approved WMO Date:	10-05-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-01-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-05-2011
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-07-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL29544.078.10