SteepRamp validation & tendon structure in DM2.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28345

Source
Nationaal Trial Register

Brief title
SteepRamp validation & tendon structure in DM2

Health condition

Diabetes Mellitus type 2

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Afdeling Revalidatie geneeskunde / Sportgeneeskunde
Intern adres: Kamer H. 026
postbus 2040
3000 CA Rotterdam
Nederland
Source(s) of monetary or material Support: The Netherlands Institute for Sport and Physical Activity (NISB) /
Nederlands Instituut voor Sport en Beweging (NISB)

Intervention

Outcome measures

Primary outcome

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 type 2 diabetes patients with the incidence in matched controls.

Secondary outcome

Substudy A:

1. Develop a regression formula to predict VO2max, daily activity pattern and quadriceps strength from SteepRamp test results in type 2 diabetes patients;

2. Obtaining reference values for physical fitness, activity pattern en quadriceps strength for type 2 diabetes patients;

3. Correlating physical fitness with the level of AGE in type 2 diabetes patients.

Substudy B:

1. Correlating muscle strength and activity pattern with Achilles tendon structure abnormalities in type 2 diabetes patients;

2. Correlating advanced glycation end-products (AGE) with Achilles tendon structure abnormalities in type 2 diabetes patients.

Study description

Background summary

N/A

Study objective

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).

Study design

Substudy A:

1. Test day 1:

A. Intake interview and examination: A sports physician will screen the patient for cardiovascular disease and musculotendinous complaints and/or injuries using a questionnaire and short clinical examination;

B. Anthropometry: Besides weight and length, body fat percentage will be estimated form skin fold measurements using the Durnin & Womersly method. Abdominal circumference will be measured at the level of the belly button;

C. Spiro-ergometric test: Performed on a cyclo-ergometer. After a 4 min. warming-up period the resistance will be increase using a 2 watt/6 sec or a 1,2 watt/6 sec. protocol for men and women respectively, resulting in approx. 10 min of exercise with resistance. The test will end with a 5 min. recovery phase. During exercise and recovery VO2, ECG, blood pressure, oxygen saturation and the rate of perceived exertion (Borg score) will be monitored;

D. Fasting venous blood sample & urine test
blood: Hemoglobin, HbA1c, plasma glucose, HDL-C, LDL-C, T-Chol, triglycerides and free fatty acids.
Blood plasma (3 ml) will be collected into EDTA containing tubes and will be centrifuged for 4 min. at 4ºC. Aliquots of plasma will be frozen immediately in liquid nitrogen and stored at -80ºC until analysis.
Urine: microalbuminuria (urine);

E. Activity monitoring: The patient will receive a validated multi-sensor accelerometer (Actigraph®) [36] and is requested to log daily activity to estimated kcal expenditure over 7 days;

2. Test day 2:

A. Sub-maximal and SteepRamp test: Within 7-14 days a sub-maximal exercise test will be performed using the following protocol: 2 min at 0,5 watt/kg, 2 min at 1,0 watt/kg and 2 min at 1,5 watt/kg. Ater 30 min a SteepRamp test will performed (3 min. warming-up phase without resistance, 25 watt/10 sec. test phase, test termination at <60 RPM). Maximal

workload and the rate of perceived exertion (Borg score) will be documented;

3. Test day 3:

A. SteepRamp and sub-maximal test: Within 7-14 days the two tests will be repeated in reversed order;

4. Test day 4:

A. Sit-to-Stand test: A standardized Sit-to-Stand test [55] will be performed. The time to complete the test will be recorded. The test is validated as a quadriceps strength test;

B. Isokinetic quadriceps strength: Quadriceps strength will be objectified with a (isokinetic) Biodex® measurement (5 repetitions at 60 gr/sec).

Substudy B:

Only for the cases and matched controls included in substudy B, for the control subjects this is the only test day.

Test day 5:
1. Skin auto-fluorescence measurement: Forearm skin auto-fluorescence will be measured using the AGE-reader® [51]. The measurement is completely automated and is obtained by placing the forearm on the device. The measurement takes approx. 1 min. to complete;

2. UTC measurement: The measurement is completely automated and is obtained by placing the lower leg in the UTC device [53, 54]. A 10 MHz linear-array transducer (Smartprobe 10L5, Terason 2000, Teratech, USA) is moved along and perpendicular to the tendon’s long axis over a distance of 9.6 cm. Images are collected at regular distances of 0.2 mm. Four echo-types were assigned, based on the stability of intensity and distribution in contiguous transverse images, namely: I) highly stable; II) medium stable; III) highly variable and IV) constantly low intensity and variable distribution. The measurement takes approx. 30 min. to complete;

3. Venous blood sample (only for control subjects) HbA1c. Blood plasma (3 ml) will be collected into EDTA containing tubes and will be centrifuged for 4 min. at 4ºC. Aliquots of plasma will be frozen immediately in liquid nitrogen and stored at -80ºC until analysis.

Intervention

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. 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 DM2 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 type 2 diabetes. Skin autofluorescence will be correlated with an ultrasonic tissue characterization (UTC) technique. To test the hypothesis a group of 30 subjects (aged 35-60 yr) 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 en gender. When the hypothesis can be confirmed, exercise intervention programs for DM2 patients can be incorporated with a tendon strengthening program if necessary.

Contacts

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Eligibility criteria

Inclusion criteria

Substudy A:

1. Type 2 diabetes mellitus >2 yr;

2. Age: 30-80 years;

3. BMI: 27-40 kg/m2;

4. 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.

1. Type 2 diabetes mellitus >2 yr;

2. Age: 35-60 years, (15 male, 15 female);

3. Formal permission to participate in the study by signing an informed consent form.

30 controls will be matched for gender and age.

Exclusion criteria

Substudy A and B:

1. Cardiovascular disease such as heart failure, cardiac ischemia or serious peripheral

vascular disease (e.g. claudicatio intermittens);

2. Serious orthopedic of neurological conditions precluding an exercise test or muscle strength test.

Substudy B:
1. Use of fluoroquinolones.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2010
Enrollment:	165
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-02-2010
Application type:	First submission

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
NTR-new	NL2092
NTR-old	NTR2209
Other	MEC Erasmus MC : 2010-066
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A