Usefulness of a modified Åstrand bicycle test for VO2 max measurement: a comparison with the regular Åstrand bicycle test in subjects with Musculo Skeletal Pain Disorders (MSPDs) and healthy subjects

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON31317

Source
ToetsingOnline

Brief title
Usefulness of a modified Åstrand bicycle test

Condition

- Other condition

Synonym
Musculo-skeletal discorders (MSDs); muscle and skeletal complaints

Health condition

Musculo-skeletale pijnklachten (oa chronische lage rugpijn, fibromyalgie)

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Blixembosch
Source(s) of monetary or material Support: Geen

Intervention

Keyword: Åstrand test, Modified Åstrand test, Musculo Skeletal Pain Disorders, VO2 max

Outcome measures

Primary outcome

Group of healthy subjects: difference of maximal volume oxygen uptake (VO2 max in mL/kg lean body mass/min (mL/kg LBM.min-1)) between the two test methods in percentages. Golden standard is the regular Åstrand test.

MSPD group: the amount of drop-outs. If possible (regarding the amount of drop-outs and the study power), the difference of maximal volume oxygen uptake between the two test methods in percentages is also a main study parameter in this group. Than also the regular Åstrand test is seen as the golden standard.

Secondary outcome

Healthy group: the amount of drop-outs

Both groups: general self-efficacy, pain (expected maximal pain during the Åstrand test and actual experienced pain during the Åstrand test), perceived exertion, and an estimation of the chance of completing the Åstrand test.

Study description

Background summary

Physical fitness level is largely determined by the aerobic capacity. In the rehabilitation setting aerobic capacity tests are frequently performed to adjust the physiotherapeutic treatment to the individual aerobic capacity, and to evaluate the process. In rehabilitation centre Blixembosch this is a standard assessment in people with Musculo-Skeletal Pain Disorders (MSPDs). Aerobic capacity is determined by measuring maximum oxygen uptake (VO2 max). For this, generally a submaximal effort test is used: the Åstrand bicycle test. In Blixembosch this test appears to be too demanding for many pain patients. As a result, they can not complete the test. In this centre a modified Åstrand test is developed, which seems easier to accomplish for the patients. However, usability of this test has not been determined yet.

Study objective

The aim of this study is to generate more reliable outcome values as basis for physiotherapeutic treatment. Therefore, we need to determine the usability of the modified test from Eindhoven, not only in healthy but also in subjects with MSPDs. Obtained VO2 max values of the modified Åstrand test will be compared to the VO2 max values of the regular Åstrand test.

Study design

First, the study has to be approved by the METC. 30 subjects with MSPD and 30 healthy subjects - who meet the in- and exclusion criteria and gave written informed consent for participation - will perform both a regular and a modified Åstrand submaximal bicycle test (cross over design). Several questionnaires will be completed regarding activity level, pain disability, self-efficacy, pain and perceived exertion.
The VO2 max values of both tests will be calculated and compared in each participant. A pared sample t-test will be performed to determine whether the outcomes match enough to call the test useful.

Study burden and risks

The risks for sub-maximal testing are low (see E9).

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

MSPD-group:
- The subjects need to be diagnosed with MSPD by their General Practitioner or Medical specialist. In this study, it only applies to specific and a-specific low back pain, specific and a-specific pelvic or lower extremity pain, chronic pain syndromes and fibromyalgia. The rehabilitation physician indicated that treatment was suitable to diminish the limitations resulting from this MSPD. At the moment of inclusion, the subject with MSPDs has to be under supervision in Rehabilitation Centre Blixembosch, Eindhoven. ;General inclusion criteria:
- Age between 30 and 65 years
- Ability to walk 100 meters without interruption

Exclusion criteria

- Not able to read and speak sufficient Dutch (because of the questionnaires)
- The use of β-blockers
- Suffering from neurological, metabolic, cardiovascular or pulmonary disease making aerobic

capacity testing impossible
- Major psychiatric conditions
- Pregnancy
- Other medical co-morbidity which impede intensive aerobic capacity testing

Study design

Design

Study type: Observational invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC SRL/iRv: St Revalidatie Limburg/iRv Kenniscentrum voor Revalidatie en Handicap (Hoensbroek)

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	NL17656.022.07