Validity of the Steep Ramp Test to assess exercise capacity in patients with cancer undergoing chemotherapy

Published: 23-07-2013
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To evaluate the validity of the SRT for assessing the exercise capacity of patients with cancer during chemotherapy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON40203

Source
ToetsingOnline

Brief title
START

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer and exercise tolerance during chemotherapy treatment

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: Stichting Achmea Gezondheidszorg (SAG)

Intervention

Keyword: Chemotherapy, Steep Ramp Test, Validity, VO2max

Outcome measures

Primary outcome

The primary outcomes will be the level of agreement between peak VO2 (VO2peak) and peak power (Wpeak) as assessed with a CPET and the peak power (Wpeak) as assessed with the SRT.

Secondary outcome

Secondary study outcomes will include fatigue and health-related quality of life (HRQOL).

Study description

Background summary

Physiotherapists use exercise diagnostics to determine patients* fitness level prior to the start of an exercise regimen, to adjust an exercise program when necessary, and to evaluate the effectiveness of such a program. Regular testing during the course of an exercise program is necessary to adjust the intensity of the exercise. A symptom limited incremental exercise test with breath-by-breath gas analysis - also know as a cardiopulmonary exercise test (CPET) - is considered to be the gold standard to assess cardiorespiratory fitness. However, this test is not available in typical primary care physiotherapy practices because of lack of expertise in this area, the inability to meet safety guidelines, and the expense of the equipment needed. The CPET can also be burdensome for the patient. In daily clinical practice, submaximal exercise tests are often used as an alternative to the CPET. These tests can be performed relatively easily by physiotherapists, are less demanding of patients, and are less expensive to perform. The Steep Ramp Test (SRT) is a submaximal test alternative to the CPET for tailoring aerobic exercise during chemotherapy treatment. The SRT has been validated in other populations, but not yet in adults with cancer undergoing chemotherapy.

Study objective

To evaluate the validity of the SRT for assessing the exercise capacity of patients with cancer during chemotherapy.

Study design

Cohort study

Study burden and risks

In total, 50 consenting patients will undergo an extra CPET and will complete a questionnaire at the start of chemotherapy (T0) and 9 weeks after the first measurement (T1).

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

Patients with cancer who will undergo chemotherapy and who have decided to participate in a physiotherapeutic intervention during their chemotherapy treatment.
Approval of treating physician to participate in this study.

Exclusion criteria

Patients with comorbid conditions which would contraindicate participation to a VO2max test.
1. Serious orthopedic conditions
2. Serious cardiovascular or cardiopulmonary conditions (or risks)
Patients with a high risk profile for cardiovascular events according to the ACSM guidelines
3. Patients suffering from malnutrition as evidenced by a BMI < 18 kg/m2, unintended weight loss of more than 5% per month, or more than 10% unintended weight loss during the previous 6 month
4. Serious psychiatric or cognitive problems
5. Lack of basic fluency in the Dutch language.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	23-07-2013
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	20-11-2013
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	16-01-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	29-04-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	26-02-2015
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL44278.031.13