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The ability of the steep ramp test to measure and monitor aerobic capacity

Submission date
25/08/2020

Recruitment status
No longer recruiting

Registration date
15/09/2020

Overall study status
Completed

Last Edited
09/08/2021

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
It is important to get insight in the aerobic capacity of cancer survivors, in order to give the appropriate training prescription and to monitor training progression. The best tool to assess aerobic capacity is a cardiopulmonary exercise test (CPET). During a CPET, it is possible to determine a person's peak oxygen uptake (VO2peak), which is the maximum amount of oxygen that can be utilized by the muscles during maximal exercise. However, performing CPET is not always feasible in daily practice. Previous studies suggest that a short maximal exercise test performed on a cycle ergometer, called the steep ramp test (SRT), might be a good alternative to estimate VO2peak in cancer survivors. However, these studies did not investigate the ability of the SRT to monitor changes in VO2peak over time. Therefore, the aim of this study was to examine the ability of the SRT to measure and monitor aerobic capacity.

Who can participate?
Cancer survivors of 18 years and older, who participate in the multidisciplinary oncology rehabilitation program at the Department of Physical Therapy of the Maastricht University Medical Center (UMC+) and completed a CPET and SRT before the start of the exercise program (T=0).

What does the study involve?
Participants are attending an exercise rehabilitation program following their cancer treatment. They perform two different exercise tests before the start of the program (T=0) and 10 weeks later at the end of the rehabilitation program (T=1). The exercise tests they have to perform are a cardiopulmonary exercise test (CPET) and a steep ramp test (SRT). The CPET is a maximal exercise test with respiratory gas analysis, which will be performed on a cycle ergometer, in which the work rate increases from unloaded cycling to the participant's maximal work rate in approximately ten minutes. During this test, participants have to wear a facemask, which is connected to a computer, in order to measure different cardiorespiratory values. This is necessary to assess a person's peak oxygen uptake (VO2peak), the primary outcome measure of the CPET. The SRT is a short maximal exercise test performed on a cycle ergometer, in which the work rate increases with 25 watts every 10 seconds until the participant is not able to keep cycling anymore. The attained maximal work rate is its primary outcome measure. In nonathletic or diseased persons, the duration of the SRT is approximately one to two minutes.

What are the possible benefits and risks of participating?
There are no benefits and risks in participating in this study. The participants perform the SRT and CPET as a part of the rehabilitation program and are only asked to give permission for the use of their usual care data.

Where is the study run from?
The department of Physical Therapy of the Maastricht University Medical Center + (Netherlands)

When is the study starting and how long is it expected to run for?
October 2018 to March 2020

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
Anouk T. R. Weemaes
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2018-0648

Study information

Scientific Title
Criterion validity and responsiveness of the steep ramp test to evaluate aerobic capacity in cancer survivors participating in a supervised exercise rehabilitation program

Study objectives
1. Based on the results of previous studies, the correlation coefficient between VO2peak measured during cardiopulmonary exercise testing (CPET-VO2peak) and peak work rate achieved during the steep ramp test (SRT-WRpeak) is expected to be positive and strong (>0.70)
2. Based on a larger degree of measurement error that comes along with repeated testing, a moderate correlation (0.50- 0.70) is expected between the change in CPET-VO2peak and SRT-WRpeak over time
3. For the same reason, the ability of the SRT to discriminate between participants who do or do not improve in aerobic capacity is expected to be moderate. As such, the area under the curve (AUC) of the receiver operating characteristics (ROC) is expected to be 0.60- 0.80

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/10/2018, Maastricht University Medical Centre+ Ethics Committee (P. Debyelaan 25 6202 AZ Maastricht, the Netherlands; secretariaat.metc@mumc.nl; +31(0) 433876009), ref: 2018-0648

Study design
Single-centre longitudinal cohort study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Aerobic capacity in cancer survivors

Interventions

Cancer survivors attending a 10-week supervised exercise rehabilitation program at Maastricht UMC+ are included in the study. Participants perform a cardiopulmonary exercise test (CPET) and a steep ramp test (SRT), at the beginning (T=0) and at the end (T=1) of the exercise program.

Not all participants were able to complete exercise tests at T=1, because these tests were postponed or cancelled due to the COVID-19 pandemic, in which all outpatient activities were cancelled for four months.

Intervention Type
Other

Primary outcome measure
1. VO2peak measured during CPET (CPET-VO2peak) using cardiopulmonary exercise testing (CPET) performed on an electronically braked cycle ergometer (Lode Corival Rehab, Lode BV, Groningen, the Netherlands) where continuous breath-by-breath analysis was obtained during the test using an ergospirometry system calibrated for respiratory gas analysis (Vyntus CPX, CareFusion, Hochberg, Germany) measured at basline (T0) and 10 weeks (T1)
2. Peak work rate achieved during the steep ramp test (SRT-WRpeak) using an electronically braked cycle ergometer (Lode Corival Rehab Lode BV, Groningen, the Netherlands) measured at basline (T0) and 10 weeks (T1)

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/10/2018

Completion date
06/03/2020

Eligibility

Key inclusion criteria
1. Cancer survivors of 18 years and older, who:
1.1. Participate in the multidisciplinary oncology rehabilitation program at the Department of Physical Therapy of the Maastricht University Medical Center (UMC+)
1.2. Complete a CPET and SRT before the start of the exercise program (T=0)
1.3. Give written informed consent for the use of their usual care performance data

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Total final enrolment
106

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2019

Date of final enrolment
06/03/2020

Locations

Countries of recruitment
Netherlands

Study participating centre
Maastricht University Medical Centre (UMC+)
Department of Physical Therapy
P. Debyelaan 25
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Sponsor information

Organisation
Maastricht University Medical Centre

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Sponsor type
Hospital/treatment centre

Website

https://www.mumc.nl/

ROR
https://ror.org/02d9ce178

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/01/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available upon request from Anouk T. R. Weemaes, PT, MsC (anouk.weemaes@mumc.nl). This concerns performance data that is already available and will be available for 15 years, but only when participants gave consent for the use of their data in future research. Only anonymized data will be shared, following the guidelines of Good Clinical Practice (GHP), with researchers in the same field of interest, when the researchers involved in this study think this leads to added value for the use of the steep ramp test or any other performance test in clinical daily practice.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/05/2021	09/08/2021	Yes	No