

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

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| Submission date 25/08/2020 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 15/09/2020 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 09/08/2021 | Condition category Other | <input type="checkbox"/> 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 (VO_{2peak}), 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 VO_{2peak} in cancer survivors. However, these studies did not investigate the ability of the SRT to monitor changes in VO_{2peak} 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 (VO_{2peak}), 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

Contact name

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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 baseline (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 baseline (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

Maastricht

Netherlands

6229 HX

Sponsor information

Organisation

Maastricht University Medical Centre

Sponsor details

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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 |