STEep Ramp test Norm values Utrecht Maastricht study

Published: 23-11-2016
Last updated: 11-04-2024

Main objective: Collecting and setting up norm values for the SRT-Wpeak for healthy young adults between 19 and 24 years. Secondary objectives: [1] Determine the reproducibility of the SRT; [2] Determine the relationship between the SRT-Wpeak and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON45715

Source
ToetsingOnline

Brief title
STERNUM

Condition

- Other condition

Synonym
healthy young adults

Health condition

cardiorespiratoire fitheid

Research involving
Human

Sponsors and support

Primary sponsor: Hogeschool Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: exercise testing, normvalues, steep ramp test, VO2peak

Outcome measures

Primary outcome

SRT-Wpeak

CPET-VO2peak

Secondary outcome

Demography (age, sex); Anthropometry (height, weight, lungfunction, % bodyfat);

Study description

Background summary

Despite its clinical relevance, the use of formal cardiopulmonary exercise testing (CPET) seems to be underused in current usual clinical practice. Currently, the Steep Ramp Test (SRT) has proven to be a reliable and valid alternative, without the need for use of respiratory gas analysis measurements. However, norm values for (young) adults are lacking and regression equations to predict peak oxygen uptake (VOpeak) out of the peak workload attained during the SRT (SRT-Wpeak) are developed in specific patients, which hampers its feasibility.

Study objective

Main objective: Collecting and setting up norm values for the SRT-Wpeak for healthy young adults between 19 and 24 years. Secondary objectives: [1] Determine the reproducibility of the SRT; [2] Determine the relationship between the SRT-Wpeak and different anthropometric parameters; [3] Determine the relationship (criterion validity) between the CPET-VO2peak and the SRT-Wpeak and different anthropometric parameters.

Study design

Observational (cross-sectional) study. Seventy healthy, young adult participants in the age between 19 and 24 years will undergo a screening procedure and perform a SRT in the Exercise laboratory of the University of Applied Sciences Utrecht. Within two weeks afterward, participants will perform a CPET (n=24) or a second SRT (n=46) based on randomization. All tests and procedures will be performed in the Exercise Laboratory of the University of Applied Sciences, Institute of Movement Studies, Utrecht.

Study burden and risks

The risks associated with study participation are negligible as the SRT is already part of usual care in higher risk patient categories as heart failure, COPD, status after chemotherapy and diabetes. Furthermore, risks associated with CPET are negligible in proper screened, young, sports participating healthy adult participants without any clinical complaints who, probably, already take part in high-intensity sports activities. The facilities of the exercise laboratory entirely fullfills the safety criteria for exercise testing in this particular population.

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

Healthy young adults between 19 and 24 years.

Exclusion criteria

* A medical status that contraindicates exercise testing (using the ACSM Risk Stratification Questionnaire)
* The use of medication affecting exercise capacity (e.g. beta block)
* Smoking
* Comorbidity that affects exercise response and exercise capacity
* Impaired motor development;
* Morbid obesity (BMI>35kg/m2);
* Insufficient understanding of the Dutch language
* Not meeting Dutch Healthy Exercise Norms (Nederlandse Norm Gezond Bewegen)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-03-2017
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	23-11-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-10-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL59559.041.16