Feasibility and repeatability of an incremental exercise test on the combined arm-leg (Cruiser) ergometer in patients with a lower limb amputation

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The first aim of this study is to evaluate 1) the feasibility and 2) repeatability of a new exercise test protocol to measure the pysical fitness of persons with a lower limb amputation on the combined arm-leg (Cruiser) ergometer.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Observational non invasive

Summary

ID

NL-OMON37936

Source
ToetsingOnline

Brief title
Exercise test in lower limb amputees

Condition

- Bone and joint injuries
- Bone disorders (excl congenital and fractures)
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
amputation of the lower limb, lower limb amputation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,OIM stichting

Intervention

Keyword: combined arm-leg ergometer, exercise test, lower limb amputation, repeatability

Outcome measures

Primary outcome

Maximal oxygen uptake (VO2max in l/min)

Secondary outcome

Gross Efficiency (% of external work performed to the total production of energy), metabolic equivalent of exercising (MET in 3.5 ml O2 /kg/min), maximal carbon dioxide output (VCO2 in liters per minute), heart rate (HR in beats per minute), maximal workload (W),blood pressure (BP in mmHg), breathing frequency (BF in breaths per minute) maximal ventilation (VE liters per minute), respiratory exchange rate (RER in %) and rate of perceiverd exertion (RPE in 10 point borg-scale)

Study description

Background summary

In studies conducted to gain more knowledge about the maximum oxygen uptake and efficiency of movement in lower limb amputees, many different methods, tests and outcome variables are used. On this moment there is no appropriate and repeatable test protocol available to measure the physical fitness in patients with a lower limb amputation

Study objective

The first aim of this study is to evaluate 1) the feasibility and 2)

repeatability of a new exercise test protocol to measure the pysical fitness of persons with a lower limb amputation on the combined arm-leg (Cruiser) ergometer.

Study design

Whitin subject design

Study burden and risks

After inclusion, subjects are asked to perform a submaximal exercise test and three peak (maximal) exercise tests on the Cruiser ergometer following a continuous exercise protocol. These trials will be conducted on three days with 1-2 weeks in between. The first trial will take about one hour, the other two trials will take half an hour.
Prior to testing, subjects will be screened for contraindications to peak exercise. During all tests supervision will be present, familiar with adverse events. Risks concerning exercise testing are proven to be very small.

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 a lower limb amputation (unilateral transfemoral amputation, knee disarticulation or transtibial amputation).

Exclusion criteria

The subjects will be excluded from this study if there is evidence or serious suspicion of coronary disease, stress or exercise related pain in the chest, untreated symptomatic arrhythmia*s (ventricular tachycardia or any rhythm significantly compromising cardiac function), hypertension with a diastolic bloodpressure of > 100 mm Hg or systolic bloodpressure > 180 mm Hg, acute pulmonary embolus, bilateral lower limb amputations or upper limb amputation, mental impairment leading to inability to cooperate or inability to obtain consent

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):	01-04-2012
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	23-08-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-05-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL34139.042.11