Physical fitness and physical strain in people after lower limb amputation during rehabilitation .

Published: 03-04-2013
Last updated: 23-04-2024

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

Summary

ID

NL-OMON40280

Source
ToetsingOnline

Brief title
Physical fitness and physical strain in people after lower limb amputation.

Condition

- Other condition

Synonym
amputation, lower limb amputation

Health condition

beenamputatie

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Wetenschappelijk college fysiotherapie (KNGF)

Intervention

Keyword: Amputation, Physical fitness, Physical strain, Rehabilitation

Outcome measures

Primary outcome

Aerobic capacity in terms of maximal oxygen uptake (ml/kg/min)

Aerobic strain in terms of heart rate reserve (%heart rate reserve)

Secondary outcome

Exercise capacity in terms of maximal mechanical power, and minimal and maximal heart rate

Aerobic strain in terms of rating of perceived exertion (Borg scale) and activity diary.

Walking ability in terms of the SIGAM mobility scales and items scored on the LCI-5 questionnaire.

Participation in terms of items scored on the USER-P questionnaire.

Study description

Background summary

People with a lower limb amputation have a large risk of physical deconditioning before, during or after amputation. Although the importance of physical fitness for functioning after amputation is well acknowledged, little objective data is available on the level of physical fitness and the chage thereof in people who undergo rehabilitation after lower limb amputation. In addition, it is unknown what level of physical strain is imposed during regular rehabilitation and whether this complies with guidelines for improving physical fitness.

Study objective

The aim of the study is to assess physical fitness of people in rehabilitation after lower limb amputation and to assess their physical strain during the regular rehabilitation program and specific (physical therapy) sessions of this program. Physical strain will be compared to accepted training guidelines for improving physical fitness. Additionally, it will be investigated how physical fitness is related to walking ability and general functioning after rehabilitation.

Study design

Patients will undergo peak exercise capacity testing at two instants during rehabilitation: at the start and end of the rehabilitation program. In addition, physical strain imposed on the these patients will be monitored during a full week at the beginning and end of the rehabilitation program. Furthermore, a telephone interview will be done half a year and a year after discharge form clinical rehabilitation to evaluate their functioning on that moment.

Study burden and risks

The study will take place within the regular rehabilitation program of the participating patients.
The exercise tests will be administered by experienced therapists and if necessary supervised by a medical doctor. Absolute and relative contra indications for maximal exercise test as postulated by the ACSM will be applied.
During the exercise tests cardiovascular stress will be monitored through blood pressure and ECG. Safety, feasibility and validity of the protocol has recently been established (Wezenberg et al 2012). In case of emergency a crash team is stand by according to regular procedures in both rehabilitation centers.

the assessment of physical strain during rehabilitation with the use of heart rate monitors will impose negligible burden to the patient.

The burden of the telephone interview done at two moments respectively half a year and a year after discharge will be a time investment of 10 minutes.

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 unilateral amputation of part of the lower limb that will be admitted to the in- or outpatient clinic of the participating rehabilitation centers

Exclusion criteria

serious cardiovascular, neurological or musculoskeletal pathology that imposes a contra-

indiaction for the execution of a maximal exercise test.

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):	22-07-2013
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	03-04-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	27-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL43218.029.13