Reliability of residual limb volume measurement in transtibial amputees using 4 different methods.

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To determine the inter- and intrarater reliability of 4 different methods to define stump volume in vivo, namely: water displacement method, Omega Tracer (Ohio Willow Wood), Design TT (Otto Bock) and circumference measurement (Sytzia-method).

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

Summary

ID

NL-OMON30489

Source
ToetsingOnline

Brief title
not applicaple

Condition

- Other condition
- Soft tissue therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Lower limb amputation, Transtibial amputation

Health condition

Amputatie onderste extremiteit

Research involving

Human

Sponsors and support

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

Intervention

Keyword: amputation, reliability, transtibial, volume measurement

Outcome measures

Primary outcome

Inter- and intrarater reliability.

Secondary outcome

not applicable

Study description

Background summary

To determine the effect of a treatment in transtibial amputees often *readiness for prosthetic fitting* is chosen as outcome variable. One of the criteria of *readiness for prosthetic fitting* is reaching a stable volume of the stump. To assess stability of a stump volume, an accurate and reliable assessment is indispensable. Different methods to measure stumpvolume are used in practice. Examination into the reliability of these methods is particularly done in vitro, by using test cilinders. Less or no research at all has been done into the reliability of these methods in vivo.

Study objective

To determine the inter- and intrarater reliability of 4 different methods to define stump volume in vivo, namely: water displacement method, Omega Tracer (Ohio Willow Wood), Design TT (Otto Bock) and circumference measurement (Sytzia-method).

Study design

A reliability study will be performed. The stump volume of 60 participants will

be measured in two occasions. Each occasion consists of 2 sessions, in each session 2 observers will do the four measuring methods. The measurements will be done by two researchers, in which each researcher carries out two measurements sessions. The sequence of the observers as well as the measurements within the sessions will be randomized.

Study burden and risks

The participants will come twice to the study location. Travelling expenses will be compensated. The expected time the measurements will take is approximately one and a half hours per occasion. The measurements won*t bring any risk to the participants.

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

1: Transtibial amputation
2: More than 12 months post-amputation
3: Informed consent
4: Patient is able to stand safe on one leg

Exclusion criteria

1: Cardiac- or renal diseases resulting in volume fluctuation of the stump

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):	17-08-2007
Enrollment:	60
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	10-05-2007
Application type:	First submission

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	NL14411.042.07