Sensibility of the stump in adults with an acquired upper extremity amputation.

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To analyse sensibility of the stump in adults with an acquired upper extremity amputation and compare the sensibility with the corresponding part of the contralateral arm and the contralateral fingers. Sensibility of the non-affected arm and fingers...

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

Summary

ID

NL-OMON33467

Source
ToetsingOnline

Brief title
Stump sensibility

Condition

- Bone and joint injuries
- Bone and joint therapeutic procedures

Synonym
Amputation

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, Rehabilitation, Sensibility, Upper extremity

Outcome measures

Primary outcome

Touch pressure, measured by Semmes Weinstein monofilamenten.

Secondary outcome

Stereognosis (Shape/texture identification test, STI-test) and kinaesthesia.

Functioning with or without a prosthesis is analysed with the Orthotics and

Prosthetics Users* Survey (OPUS).

Study description

Background summary

Rejection of upper extremity prostheses and subsequent non-use is observed in approximately 1 of every 5 individuals with upper extremity amputation. A reason for not using a prosthesis after an upper extremity amputation might be the lack of tactile feedback. Little is known about stump sensibility. Cortical reorganization in the brain might change the sensibility in the stump. Until now, it is unknown whether sensibility changes after amputation. Furthermore the relation between sensibility and functionality is unknown.

Study objective

To analyse sensibility of the stump in adults with an acquired upper extremity amputation and compare the sensibility with the corresponding part of the contralateral arm and the contralateral fingers. Sensibility of the non-affected arm and fingers of the patients will be compared to the sensibility of de corresponding arm of the control subjects. If there is a difference in sensibility, is there an association with prosthetic use and time after amputation? Is there a relation between sensibility and functioning in daily activities?

Study design

A cross-sectional study

Study burden and risks

No risks.

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:
* Unilateral acquired upper extremity amputation (an exarticulation of the wrist and more proximal amputation levels)
* At least 1 year after amputation
* Aged: 18 +;Control subjects:
* Healthy subjects

* Matched for age-, sex- and hand dominancy

Exclusion criteria

Patients and control subjects:
Medical history of diminished sensibility: Vascular disease, DM, Neurological disease with loss of sensibility (polyneuropathy, peripheral nerve damage)
CRPS
Bilateral amputation
Patients with insufficient understanding of the Dutch language

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-07-2009
Enrollment:	62
Type:	Actual

Ethics review

Approved WMO

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	NL26772.042.09