Cost-efficiency of myoelectric upper limb prostheses

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21884

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Upper limb defects, including both amputations and congenital deficits.

Sponsors and support

Primary sponsor: NA
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Cost-utility calculated with the Multi-Attribute Preference Response (MAPR) and total costs from a societal perspective, shown as an incemental cost-effectiveness ratio

Secondary outcome

- Box & Block test
- Southampton Hand Assessment Procedure (SHAP)
- Movement analyses focussed on compensation
- Dutch user Quebec evaluation score (D-QUEST)
- Trinity Amputation and Prosthesis Experience Scales (TAPES)
- Orthotics and prosthetics user survey (OPUS)
- Quality of life (RABD-36 & EQ-5D)
- MAPR-score
- Average costs from the SMP and MMP from a societal perspective

Study description

Background summary

Last decade costs of health care related to upper limb prosthesis in the Netherlands are raising. The introduction of innovative types of prostheses, like the multi-articulated myoelectric prosthesis (MMP) with moveable thumb and fingers, seems to be one of the causes for this raise. MMPs have functional advantages, but also have disadvantages: less durable, difficult to control, and more expensive. Probably, for some persons, a more simple prosthesis would meet their expectations as well. Current literature about the cost-efficiency of upper limb prosthesis is limited. Therefore the aim of this study was to compare the efficacy, cost-efficiency, and cost-utility of the 'standard' myoelectric upper limb prosthesis (SMP) with the MMP. We will perform a cross-sectional study with a limited cross-over design, which exists of two phases. In the first phase, MMP users are performing several tests with the MMP and SMP to compare the efficacy of these prostheses. In the second phase, persons with an MMP and persons with an SMP are asked to complete surveys about the costs of their prosthesis and all costs related to the prosthesis, quality of life, users' value of the prosthesis, and satisfaction with the prosthesis.

Study objective

We hypothesize that the MMP could be cost-efficient for a part of the patients, but that for some patients a more simple prosthesis would be more cost-efficient. Therefore, we do not expect big differences in cost-effectiveness between the MMP and SMP.

Study design

Sep 2020: Start inclusion
Okt - Dec 2020: Measurements
Jan - Mar 2021: File investigation

Intervention

NA

Contacts

Public
Universitair Medisch Centrum Groningen
Nienke Kerver

+31503613553
Scientific
Universitair Medisch Centrum Groningen
Nienke Kerver

+31503613553

Eligibility criteria

Inclusion criteria

Inclusion criteria phase 1 & 2- MMP group:
- Age 18 years or older
- At least one year experience with an MMP, type be-bionic, I-limb or VINCENT
- Owner of an MMP, type be-bionic, I-limb or VINCENT
- The person is in a stable phase of the prosthesis provision process
- Sufficient command of the Dutch language to follow instructions and complete questionnaires

Inclusion criteria phase 2 - SMP group:
- Age 18 years or older
- At least one year experience with an SMP with one grip mode
- Owner of an SHP with one grip mode
- The person is in a stable phase of the prosthesis provision process
- Sufficient command of the Dutch language to follow instructions and complete questionnaires

Exclusion criteria

Exclusion criteria phase 1 & 2- MMP group:
- Co-morbidities that could influence the results of this study, like neurological disorders, rheumatic diseases, and other disorders that could affect the arm function
- Owner of an MMP, type Michelangelo

Exclusion criteria phase 2 - SMP group:
- Co-morbidities that could influence the results of this study, like neurological disorders,

rheumatic diseases, and other disorders that could affect the arm function

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2018
Enrollment:	17
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
If possible and in compliance with privacy regulations, we will release fully anonymized/pseudominized data of this study (semi-)public. If needed, there will be requirements to get acces to the data. Importantly, only the data of participants who agreed on their informed consent with (semi-)public disclosure of the data will be released.

Ethics review

Positive opinion

Date:	26-06-2020
Application type:	First submission

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
NTR-new	NL8730
Other	Medical Ethics Review Board of the University Medical Center Groningen (UMCG) : METc2018/582

Study results