Effective care of lower limb prostheses

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21556

Source
NTR

Brief title
TBA

Health condition

limb amputation

Sponsors and support

Primary sponsor: not applicable
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Prosthesis Evaluation Questionnaire, Utrechtse Schaal voor Evaluatie van Revalidatie-Participatie (USER-P), activity monitor

Secondary outcome

Short Questionnaire to assess health-enhancing physical activity (SQUASH), 6 Minutes Walking Test (6MWT), Timed Get Up en Go Test (TGUGT), Activities-Specific Balance

Confidence Scale (ABC)

Study description

Background summary

A correct choice of the components of the prosthesis is of great importance for the best possible outcome of the rehabilitation process. An important innovation for patients with a lower limb amputation through or above the knee is the development of auto-adaptive knee units (AAKs). The total annual costs per user of a leg prosthesis have increased by 37% over the last 5 years: from € 3,110 in 2012 to € 4,260 in 2016. Whether this increase in costs is related to more frequent prescribing of (a more expensive) AAK, and whether this cost increase also leads to an increase in effectiveness, has not been investigated so far. In this study we compare the effectiveness and cost-effectiveness of an AAK with that of a conventional mechanical prosthetic knee (CMK). In addition, we determine the (cost)effectiveness of integrated care with regard to lower limb prostheses by examining the extent of appropriate use of the lower limb prosthesis in relation to the costs of integrated care. Appropriate use is the effective use of the most adequate lower limb prosthesis, tailored to the real needs of the user. To implement the knowledge in clinical practice, we develop an online decision aid for users of lower limb prostheses and a national database for caregivers in order to optimally meet the needs and possibilities of the user to match the characteristics of the prosthesis.

Study objective

Appropriate use and prescription of a lower limb prosthesis for people with leg amputation through or above the knee, can increase the efficiency of the integrated care around the leg prosthesis.

Study design

Baseline, 3 AAK en 3 CMK measure points

Intervention

autoadaptive prosthetic knee

Contacts

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Eligibility criteria

Inclusion criteria

- age> 18 years
- unilateral transfemoral amputation or knee articulation> 1 year ago
- prosthetic device with CMK in a stable phase
- Medicare Functional Classification K level 2-4 (i.e. the participant is at least able to walk outside with or without
walking aid over uneven ground and can climb stairs)
- sufficient understanding of the Dutch language to be able to follow instructions and to complete questionnaires
- one of the two indications for AAK as described in detail in the AAK addendum to the PPP protocol: 1. need for extra security and stability, 2. high dynamic use

Exclusion criteria

not applicable

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2019
Enrollment:	35
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Not applicable

Application type:	Not applicable

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	NL7887
Other	METC UMCG : in progress

Study results