Functional mobility in patients with a unilateral transfemoral amputation: a comparison between the ReMotion Knee and polycentric mechanical knees currently used in healthcare.

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To compare the functional mobility of transfemoral amputation or knee exarticulation patients when using the ReMotion Knee and their current prosthetic knee. An additional aim is to examine the influence of the patient*s mobility level on the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON47968

Source
ToetsingOnline

Brief title
Mobility of transfemoral amputation patients: comparing prosthetic knees

Condition

- Bone and joint therapeutic procedures

Synonym
above-knee amputation, transfemoral amputatation

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Innovatiefonds Stichting Sint Maartenskliniek

Intervention

Keyword: amputation, artificial limb, rehabilitation, walking

Outcome measures

Primary outcome

The main study parameter is the difference in time (s) it takes the participant to finish the L-test between the two conditions. The test includes standing up and sitting down, twenty meters of straight walking and four turns, of which one is over the side of the prosthetic leg.

Secondary outcome

Secondary study parameters are gait quality, balance, precision stepping, performance of advanced walking tasks and patient experience. Gait quality is defined by walking speed, step length and %single limb support time. This will be measured using Intertial Measurement Units (IMUs) on the trunck and the feet. Balance is measured using the Berg Balance Score and the load distribution during static stance. Precision stepping will be measured using the Four Square Step Test. Advanced walking tasks are assessed using the EFAP, which combines a transfer (TUG), regular walking and advanced walking tasks. Finally, patient experience will be measured using an Numeric Rating Scale (NRS) to score the comfort, performance, fatigue and trust in balance using both proshtetic knees. After all the measurements, the participants are asked

which prosthetic knee has their preference on each of these items.

Study description

Background summary

Ambulatory mobility and function are important aspects in the quality of life of people with lower limb amputations and prostheses. Regaining mobility is often challenging, especially for patients with transfemoral, or above-knee amputations. In clinical practice, the patient*s mobility level the intended use of their prosthesis determine which prosthesis is the best fit for them. In the past decades, new types of knee prosthetics have entered the market. The standard care in Europe and the US at this moment is the mechanical, or non-microprocessor controlled, knee (NMPK). While the production costs of these NMPK*s are lower than those of the MPK*s (microprocessor controlled knee), consumer prices still reach up to $5000. Recently, the ReMotion Knee ($80) was developed as a new and affordable alternative to the currently available mechanical knees. The ReMotion Knee is mostly used in low-income, but has now received the CE mark. However, research about functional mobility and user experiences with the knee is very limited, especially in our western society.

Study objective

To compare the functional mobility of transfemoral amputation or knee exarticulation patients when using the ReMotion Knee and their current prosthetic knee. An additional aim is to examine the influence of the patient*s mobility level on the difference in functional mobility between the two prosthetic knees.

Study design

Randomized crossover trial.

Intervention

Participants perform a set of functional measurements twice: once using the ReMotion Knee and once using their own prosthetic knee.

Study burden and risks

Participants visit the research site once for 3-4 hours. During their visit they perform a set of functional measurements twice, once with their current prosthetic knee and once with the ReMotion Knee. The knees will be exchanged by

an experienced prosthetist. To familiarize with the ReMotion Knee, a training session is held under supervision of a physical therapist. If the participant has a high risk of falling, the measurements will be held in the Zero-G (zero gravity support), which has a passive fall prevention mechanism.

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

- Age >18
- Unilateral transfemoral amputation or knee exarticulation
- Activity level K2 or K3
- Time after amputation >1 year
- ReMotion Knee can be connected to the participant*s own socket
- Originally using a polycentric non-microprocessor controlled prosthetic knee

- Written informed consent

Exclusion criteria

- Complaints of pain of the residual stump.
- Severe contractures affecting the hip range of motion
- Other impairments that cause an increase in pain or a decrease in walking ability when standing and/or walking for thirty minutes
- Weight >80 kg (weight limit of the ReMotion Knee is 80 kg)
- Osseointegrated prosthesis (no socket)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-02-2019
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	ReMotion Knee
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	15-01-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-03-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL67281.091.18