MyLeg System: The functional evaluation of a powered knee-ankle prosthesis prototype for osseointegrated transfemural amputees

Published: 30-08-2022
Last updated: 17-01-2025

To evaluate the functioning of and experience using the newly-developed prototype prosthesis (MyLeg System) during daily activities in people with a transfemoral osseointegration implant.

Ethical review	Approved WMO
Status	Completed
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON52253

Source
ToetsingOnline

Brief title
MyLeg System

Condition

- Joint disorders

Synonym
Above-knee amputation, transfemoral amputation

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: EU Horizon 2020

Intervention

Keyword: Amputation, Osseointegration, Prosthesis, Prototype

Outcome measures

Primary outcome

The main study parameters are subjective evaluation of the functionality of the prosthesis and the participant*s experience are evaluated by the answers on the user report.

Secondary outcome

In addition, heart rate, and the symmetry index for spatiotemporal, kinetic and kinematic parameters will be evaluated.

Study description

Background summary

People with a transfemoral amputation experience a higher metabolic cost and cognitive load during walking. This is mainly due to the absence of an active knee and ankle. To resolve these challenges, a fully active, and intuitive prototype prosthesis has been developed using new materials with a higher energy storage capacity, a smart control system, and EMG to identify intent. The prototype prosthesis is able to generate power during highly active daily activities (i.e. climbing stairs), making knee power generation approximate the knee power generation of able-bodied people and a prosthesis which is more intuitive to use during daily life. Measurements will be done to confirm if the design of the prototype is adequate and attains the pre-set goals.

Study objective

To evaluate the functioning of and experience using the newly-developed prototype prosthesis (MyLeg System) during daily activities in people with a transfemoral osseointegration implant.

Study design

Explorative observational cross-sectional study.

Intervention

An introduction and practice with the MyLeg System inside the Radboudumc under supervision of a physiotherapist, researcher, orthopaedic technician, and the manufacturer.

Study burden and risks

The participants are asked to visit 4 days of maximal 8 hours, with a compensation in minimal wage. During the day, participants are asked to perform activities like standing, sitting, level and hill walking, and stepping on a step, whereof the risk and burden for the subjects are minimal. During this day, participants are asked to use newly-developed knee-ankle prosthesis. The use of this prosthesis prototype can cause discomfort. Walking with the new prototype can feel uncomfortable, mostly at the beginning of practice with the prototype. The use and getting used to a new prosthesis, like this prototype, may also cause muscle strain. Although the prosthetic prototype has been extensively tested for safety and use, the unlikely event that the prototype may break could cause a participant to fall. However when using the prototype, the participants will always wear a safety-harness, which will prevent them from harm in the event of a fall. In addition, the researcher and physical therapist will always be present and next to the participant during the day to prevent a fall from happening.
This research has the potential to provide an objective evaluation of the design and build of the newly-developed prosthesis in relation to the former prototypes (MyLeg P1, register number NL2019-5920 & MyLeg P2). This knowledge will be used to further develop and improve the prosthesis prototypes within and outside the MyLeg project (ERC-H2020 n.780871).

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

18 year or older and able to provide informed consent.
Underwent a uni-lateral transfemoral amputation and underwent a surgery implementing the osseointegration
implant more than 2 years ago.
Able to walk independently (MFC-level K3 or higher)

Exclusion criteria

Vascular, neurological or musculoskeletal conditions or medication affecting balance or gait
Patients with psychiatric disorders
Weight > 100 kg
Current problems with the alignment of the prosthesis
Fitted with a new prosthesis knee-component within the last 3 months or with a new prosthesis ankle-component
within the last month

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	29-11-2022
Enrollment:	1
Type:	Actual

Medical products/devices used

Generic name:	MyLeg System
Registration:	No

Ethics review

Approved WMO Date:	30-08-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-10-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-11-2022
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	NL78465.091.22

Study results

Date completed: 23-12-2022

Results posted: 23-12-2022

Actual enrolment: 1

First publication
23-12-2022