MyLeg P1: The functional evaluation of a ankle prosthesis prototype for osseointegrated transfemural amputees

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To evaluate the performance of the newly-developed prosthesis (prototype) during walking in people with a transfemoral osseointegration implant. This will be done using lab-based measurement, evaluating metabolic cost, walking capacity, gait pattern...

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

Summary

ID

NL-OMON48203

Source
ToetsingOnline

Brief title
MyLeg P1

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: Horizon 2020

Intervention

Keyword: Amputation, Osseointegration, Prosthesis, Prototype

Outcome measures

Primary outcome

The main study parameters are oxygen consumption, walking distance, and the symmetry index for spatiotemporal, kinetic and kinematic parameters.

Secondary outcome

Functionality is captured in number of stumbles during walking and the answers on the user report. The participant*s experience by the answers on the user report.

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 passive, energy efficient and lightweight prototype prosthesis has been developed. Using new materials with a higher energy storage capacity, the prototype prosthesis is able to store and release more power during push-off than conventional ankle devices. Making the push-off power better approximate to the push-off power of able-bodied people. 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 performance of the newly-developed prosthesis (prototype) during walking in people with a transfemoral osseointegration implant. This will be done using lab-based measurement, evaluating metabolic cost, walking capacity, gait pattern, functionality, and participant*s experience.

Study design

This study design includes a pre-test in the morning (with the participant*s

own prosthesis), an introduction and familiarisation period with the new prototype and a post-test in the afternoon.

Intervention

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

Study burden and risks

The participants are asked to visit once for a full day (8 hours). During the day, participants are asked to perform activities like standing sitting and walking, whereof the risk and burden for the subjects are minimal. After the pre-test, participants are asked to use newly-developed prosthesis ankle. 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 foot prototype has been extensively tested for safety and use, the unlikely event that the prototype may break could cause a participant to fall. However, the researcher and physical therapist will always be present and next to the participant during the day to prevent this. During the pre- and post- test, the participants will wear a safety-harness, which will prevent them from harm in the event of a fall.

This research has the potential to provide an objective evaluation of the design and build of the newly-developed prosthesis in comparison to the currently used prosthesis. This knowledge will be used to further develop and improve the improve the consecutive prototypes in 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):	15-02-2020
Enrollment:	4
Type:	Actual

Medical products/devices used

Generic name:	Passive transfemural ankle prosthesis prototype
Registration:	No

Ethics review

Approved WMO

Date:	16-01-2020
Application type:	First submission
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	NL69320.091.19