Evaluation of a new powered knee prosthesis

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25551

Source
NTR

Brief title
REBOOCON_ILK

Health condition

Transfemoral amputee, healthy subjects wearing the ILK using an L-shaped socket

Sponsors and support

Primary sponsor: Universiteit Twente
Biomedische werktuigbouwkunde
Drienerlolaan 5
7522 NB Enschede
Source(s) of monetary or material Support: Reboocon Holding B.V.
Hendrik Tollensstraat 84
2624 BJ Delft

Tel.: +31 6 21906453
Mail: mskytop@hotmail.com

Intervention

Outcome measures

Primary outcome

- Self-selected preferred walking speed

- Fastest walking speed

- Metabolic energy consumption during walking at comfortable walking speed

- Borg-Scale after completion of each movement activity

- Relevant subscores of the Prosthesis Evaluation Questionnaire (Usefullness, Appearance, Sounds, Ambulation)

- Hill Assessment Index

- Stair Assessment Index

- Time to complete the L-test

- Time to complete the Four Square Step Test

Secondary outcome

- Data from all sensors of the IntelLeg Knee

- Classification accuracy of intent recognition algorithms using the IntelLeg Knee

- Joint angles

- Muscle activity

Study description

Background summary

This study evaluates the performance of a new powered knee prosthesis, the Reboocon IntelLeg Knee, compared to the current state of the art (i.e. passive auto-adaptive prostheses). The study will be evaluated on 10 unilateral transfemoral amputees. The evaluation will be based on questionairres (parts of the Prosthesis Evaluation Questionairre and the Borg RPE score), biomechanical measures (kinematics, kinetics and EMG) and standardized tests for prostheses (e.g. L-test).

Study objective

The study is performed to verify if the Reboocon IntelLeg Knee has benefits compared to passive microprocessor controlled knees. We believe the IntelLeg Knee

- improves symmetry (kinematics + kinetics)

- reduces the cost of transport for walking (metabolic energy consumption)

- reduces the rate of perceived effort (Borg RPE score)

- improves scores on standardized tests, such as the hill assessment index (HAI), the stair assessment index (SAI) and the L-test.

Study design

All data is recorded during the execution of movement tasks.

Intervention

Study is designed as an A-B-A study, in which A is the subject's daily use prothesis and B the Reboocon ILK.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

- Aged between 18 and 65.

- Weight below 100 kg.

- Body length between 1.51 and 1.95 m.

- Unilateral transfemoral amputation or knee disarticulation.

- Functional level from K2 to K4

o Level 2: The patient has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.

o Level 3: The patient has the ability or potential for ambulation with variable cadence. Typical of the community ambulatory who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

o Level 4: The patient has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

- Able to perform low to moderate vigorous physical activity for a duration of 3 hours including breaks.

- At least one year after amputation.

- Willing to commit to a series of 1 or 2 training sessions of approximately 1.5 hours to get adjusted to the IntelLeg Knee.

- Current prosthesis is a passive microprocessor controlled knee.

Exclusion criteria

- Not willing to consent to participate in the study.

- Other musculoskeletal problems influencing walking ability.

- Stump problems/bad socket fitting

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2019
Enrollment:	10
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 49303
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7477
NTR-old	NTR7719
CCMO	NL68471.044.18
OMON	NL-OMON49303

Study results