Evaluation of a new powered knee prosthesis

Gepubliceerd: 14-01-2019 Laatst bijgewerkt: 15-05-2024

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…

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25551

Bron
NTR

Verkorte titel
REBOOCON_ILK

Aandoening

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

Ondersteuning

Primaire sponsor: Universiteit Twente
Biomedische werktuigbouwkunde
Drienerlolaan 5
7522 NB Enschede
Overige ondersteuning: Reboocon Holding B.V.
Hendrik Tollensstraat 84
2624 BJ Delft

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

All data is recorded during the execution of movement tasks.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Not willing to consent to participate in the study.

- Other musculoskeletal problems influencing walking ability.

- Stump problems/bad socket fitting

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2019
Aantal proefpersonen:	10

Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49303
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten