The Ideal Prosthesis Selection

No registrations found.

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

Summary

ID

NL-OMON28616

Source
NTR

Brief title
TIPS

Health condition

Persons with an upper leg amputation

Sponsors and support

Primary sponsor: Research department of a rehabilitation centre
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Part I
- Spatiotemporal variables such as stance/swing phase duration of double support phases.
- Bilateral joint angle excursions of the hip, knee, and ankle.
- Amount of energy produced and/or absorbed at the hip of the prosthetic leg and the joints of the intact leg.
- Muscle activity patterns of muscles of both the stump and intact leg.

- Energy cost of walking.

Part II:
- Spatiotemporal variables such as stance/swing phase duration of double support phases.
- Bilateral joint angle excursions of the hip, knee, and ankle.
- Prosthesis-related quality of life
- Balance confidence
- Performance-based measures of mobility.
- Participation.

Part III:
Bilateral joint angle excursions

Secondary outcome

Part I:
- Possible relationships between baseline and/or gait characteristics and the gait pattern while walking with different prosthesis.
- Clinical applicability of a novel fully ambulatory gait analysis system.

Study description

Background summary

Numerous factors are taken into account when prescribing prostheses. First of all, the physiatrist will try to determine what the (potential) activity level is or will be. In addition, preferences of the patient are taken into account. Thirdly, external factors may be of influence, for instance the policy of the insurance company of the patient. Finally, scientific evidence regarding the influence of a prosthesis on the walking pattern should be taken into account. When looking in the literature with respect to which prosthesis should be prescribed for which patient, a limited amount of studies are available. Based on this, the CBO guideline 'Amputation and prosthetics of the lower extremity' states that 'what type of prosthesis for which type of patient' is one of the essential research questions for the foreseeable future. In recent years, the added functionality of different prostheses has been increasingly studied. However, usually overall results are presented and relationships between the effect of the prosthetic knee and individual characteristics are scarcely studied. Because of this, it is unknown which type of patient benefited the most of the studied prosthetic knee. Next to this, previous research almost exclusively focused on patients with a stable gait pattern (usually one year after amputation is used as an inclusion criteria). Because of this, little is known about the restoration of walking ability. Knowledge of this is essential for the determination of the potential functional activity level of the patient. Finally, little is known about how the gait pattern of patients with an amputation can be reliably quantified. Usually 10-15 steps are collected and averaged and it is assumed that these steps are representative of the gait pattern. The TIPS project aims to gain insight into the added functionality of

different prosthetic knees and the restoration of the gait pattern, taken the above stated concerns into account.

Study objective

Part 1: Quantification of individual patient-prosthesis interactions
- Determination of the instantaneous effect of prosthetic knees with variable biomechanical properties on the gait pattern of persons with an upper leg amputation (Part Ia).
- Determination of the influence of the Total Knee versus an adaptive prosthesis on the gait pattern of persons with an upper leg amputation based on the relation between the individual needs of the persons with an upper leg amputation and the proposed function of these prosthetic knees (Part Ib).

Part 2: Restoration of walking ability within the first year after amputation
Exploration of the natural restoration of walking ability of persons with an upper leg amputation within the first year after amputation.

Part 3: Inter- and intrasession variability of gait
Determination of the inter- and intrasession variability of gait of persons with an upper leg amputation.

Study design

Part I:
Measurements will take place directly after prosthetic fitting (instantaneous effect) and after four weeks (longitudinal effect).

Part II:
Measurements will take place two weeks after prescription of provisional prosthesis, two weeks after provision of prosthesis and at the end of the treatment in the outward department.

Part III:
No specific endpoints.

Intervention

Part I:
Participants will walk with five different prosthetic knees with varying biomechanical characteristics. The instantaneous effect of these prosthetic knees on the gait pattern will be determined. Next to this the longitudinal effect of two prosthetic knees on the gait pattern will be determined.

Part II and III
No intervention. These parts are strictly observational.

Contacts

Public
Roessinghsbleekweg 33b
Erik Prinsen
Enschede 7522 AH
The Netherlands
+31 (0)53 4875761
Scientific
Roessinghsbleekweg 33b
Erik Prinsen
Enschede 7522 AH
The Netherlands
+31 (0)53 4875761

Eligibility criteria

Inclusion criteria

Part I and III
- Aged 18 or above
- Unilateral transfemoral amputation or knee disarticulation
- Functional level of K3 or K4
- At least one year after amputation

Part II:
- Aged 18 or above
- Unilateral transfemoral amputation or knee disarticulation
- Subject is expected to regain walking ability

Exclusion criteria

- Other musculoskeletal problems influencing walking ability
- Stump problems/bad socket fitting
- Severe cognitive problems

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-04-2014
Enrollment:	29
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL4330
NTR-old	NTR4478

Register	ID
CCMO	NL.47202.044.13

Study results