# **The Ideal Prosthesis Selection**

Published: 29-04-2014 Last updated: 24-04-2024

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 PULAs (Part Ia). - Determination of the influence of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

# **Summary**

### ID

NL-OMON40432

**Source** ToetsingOnline

Brief title TIPS

# Condition

• Bone disorders (excl congenital and fractures)

**Synonym** Amputation

**Research involving** Human

# **Sponsors and support**

Primary sponsor: Roessingh Research and Development Source(s) of monetary or material Support: ZonMW - Projectnr: 104002005

### Intervention

Keyword: Amputation, Biomechanics, Gait, Prosthesis fitting

### **Outcome measures**

#### **Primary outcome**

#### Part 1a

- 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 1b

- 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
- Prosthesis-related quality of life
- Balance confidence
- Performance-based measures of mobility

#### Part 2

- 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
- Prosthesis-related quality of life
- Balance confidence
- Performance-based measures of mobility

#### Part 3

Inter- and intrasession variability of gait

#### Secondary outcome

Part 1

- Relationships between baseline characteristics and the effect of the

prosthetic knee on the gait pattern

- Clinical applicability of a new fully ambulant gait analysis measurement

system

#### Part 2

Not relevant

Part 3

Not relevant

# **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 PULAs (Part Ia).

- Determination of the influence of the Total Knee versus an adaptive prosthesis on the gait pattern of PULAs based on the relation between the individual needs of the PULA 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 PULAs within the first year after amputation.

Part 3: Inter- and intrasession variability of gait Determination of the inter- and intrasession variability of gait of PULAs.

#### Study design

Part 1 Crossover study

Part 2 Prospective observational study

Part 3 Observational study

#### Intervention

Part 1a

Participants will walk with prosthetic knee from the following five categories for a short period of time. The categories are:

- Constant resistance against flexion/extension and servo-assisted extension (swing phase control). An example is, amongst others, the 3R20.

- Polycentric knee with dorsally placed joint of rotation without resistance (stance phase control) in combination with constant damping against flexion and servo-assisted extension (swing phase control). An example is, amongst others, the 3R106.

- Polycentric knee with dorsally placed joint of rotation without resistance (stance phase control) in combination with variable resistance and damping against flexion/extension depending on angular velocity and servo-assisted extension (swing phase control). An example is, amongst others, the Total Knee 2000.

- Single knee axis with variable resistance and/or damping based on ground reactive force and flexion angle (stance phase control) in combination with variable resistance and damping against flexion/extension depending on angular velocity and servo-assisted extension (swing phase control). An example is, amongst others, the Mauch SNS.

- Single knee axis with variable resistance and adaptive control (stance phase control) in combination with variable resistance and damping against flexion/extension and adaptive control (swing phase control). An example is, amongst others, the Rheo Knee.

The order in which prosthetic knees are tested will be randomized.

#### Part 1b

Participants will walk with the Total Knee and an adaptive prosthetic knee for a period of four weeks.

The order in which prosthetic knees are tested will be randomized.

Part 2 No intervention Part 3 No intervention

#### Study burden and risks

The burden associated with participation is relatively small, as we focus exclusively on walking. Participants are asked to walk multiple times (maximal five minutes at a time).

In case participants are not fully accustomed to a prosthesis there is a risk of falling. This risk, however, is comparable to the risk participants have in daily life.

To reduce the risk of falling there will be an experienced physiotherapist present during the measurements. He can assess the risk of falling at any moment.

# Contacts

#### Public

Roessingh Research and Development

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# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Adults (18-64 years)

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Elderly (65 years and older)

### **Inclusion criteria**

Part I and III

- Aged 18 or above
- Unilateral transfemoral amputation or knee disarticulation
- Functional level from K3 to K4
- At least one year after amputation;Part II:
- Aged 18 or above
- First 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
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

# Recruitment

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NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	14-08-2014
Enrollment:	39
Туре:	Actual

# Medical products/devices used

Generic name:	prosthetic knees
Registration:	Yes - CE intended use

# **Ethics review**

Approved WMO Date: Application type: Review commission:

29-04-2014 First submission METC Twente (Enschede)

# **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

 Other
 4478

 CCMO
 NL47202.044.13