The functional added value of microprocessor-controlled knee joint for amputees over the age of 65, a pilot study

Gepubliceerd: 07-06-2017 Laatst bijgewerkt: 15-05-2024

It is hypothesized that everyday activities could be performed more independently and safely with the Kenevo knee joint than with their existing prosthetic knee joint for elderly patients who have undergone an above-knee amputation or knee...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21779

Bron
NTR

Verkorte titel
KENEVO-trial

Aandoening

(lower limb) amputation

(been) amputatie

Ondersteuning

Primaire sponsor: Adelante Zorggroep, Department Center of Expertise of Rehabilitation and Audiology

Overige ondersteuning: Otto Bock Healthcare Products GmbH

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Actual level of independence in everyday life activities will be evaluated with the ‘The Assessment of Daily Activity Performance in Transfemoral amputee test’ (ADAPT). The ADAPT objectively measures functional performance in time (seconds, s) in daily life. Timepoints: baseline and at 1, 2, 14, 15, 16 and 28 weeks

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale/Objective:

The number of elderly people in the Netherlands is growing and will grow further in the future, mainly because of increased life expectancy. This is particularly true for the province of Limburg. Older people value being able to live independently for as long as possible, but this requires good health. In recent decades, the health of the elderly has improved greatly, particularly in regard to cardiovascular care. This has meant that patients with severe peripheral vascular disease undergo amputation later in life. The total number of these patients are increasing. The treatment for these patients is primarily medical support by geriatricians and treatment using therapies and aids by a rehabilitation physician/team. The development of tools such as leg prostheses has accelerated. In the last few decades, computer-controlled knee prostheses have been designed for active younger patients with a leg amputation. Recently, this technology has also been used in a knee prosthesis for older patients. Research indicates that the prosthesis leads to improved impairment levels (gait parameters such as step length), but so far no research has been done on improving activity and participation levels, which better reflect the patient’s daily life. “Activities” refers to aspects of a person’s actions, such as self-care, standing, walking and participation that underpin their participation in social life (work, hobbies, exercise).
To summarise, the problem addressed in this study is whether geriatric amputees can be more independent in their everyday life activities if their prosthesis is optimised by using a microprocessor-controlled prosthetic knee joint with specific biomechanical properties aimed at specifically supporting everyday movements.
The aim of this pilot study is to see to what extent elderly transfemoral or knee-disarticulated amputees are more independent in their everyday life activities if they use a Kenevo knee joint instead of their current one.

Study design:

This pilot study is a randomised crossover repeated measures study.

Study population:

Ten patients of at least 65 years with an unilateral transfemoral amputation or knee disarticulation in the past followed by a rehab programme, who have a comfortable walking speed of 0.2-0.8 m/s.

Intervention:

A microprocessor-controlled prosthetic knee joint, called Kenevo, specifically developed for elderly amputees.

Main study parameter/endpoint:

Actual level of independence in everyday life activities. This will be measured using the Assessment of Daily Activity Performance in Transfemoral amputee test.

Doel van het onderzoek

It is hypothesized that everyday activities could be performed more independently and safely with the Kenevo knee joint than with their existing prosthetic knee joint for elderly patients who have undergone an above-knee amputation or knee disarticulation in the past, and who suffer limited activity in and around the house.

Onderzoeksopzet

baseline and at 1, 2, 14, 15, 16 and 28 weeks

Onderzoeksproduct en/of interventie

The intervention used is a microprocessor-controlled prosthetic knee joint, called Kenevo (Otto Bock GmbH, Vienna, Austria), developed for geriatric amputees.

Contactpersonen

Publiek

Adelante Kenniscentrum

Bea Hemmen
Zandbergsweg 111

Hoensbroek 6432CC
The Netherlands
+31 45 5282358

Wetenschappelijk

Adelante Kenniscentrum

Bea Hemmen
Zandbergsweg 111

Hoensbroek 6432CC
The Netherlands
+31 45 5282358

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

o Age 65 years and older.

o Unilateral above-knee amputation or knee disarticulation.

o Have completed an active rehabilitation program in the past

o Wearing prosthesis.

o Comfortable walking speed between 0.2-0.8 m/s

o Limited activity in and around the house.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

o Additional severe orthopaedic, rheumatologic or neurological impairments that may impede gait-related performance.

o Severe perceptual or cognitive impairments.

o Lack of understanding of the Dutch language (in view of e.g. questionnaires used).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	16-02-2017
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-06-2017

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42992
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6282
NTR-old	NTR6456
CCMO	NL57678.015.16
OMON	NL-OMON42992

Resultaten