Randomized prospective evaluation of the clinical use of the Keep Walking Femoral Implant in European countries

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The primary objective is to obtain post-market clinical data according to the requirements of the MEDDEV 2.21/2 in order to fulfil 18 post-market surveillance (PMS) obligations according to Section 3.1 of Annex II, 19 Section 3 of Annex IV, Section…

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON46756

Source
ToetsingOnline

Brief title
Randomized evaluation Keep Walking Femoral Implant

Condition

- Bone and joint therapeutic procedures

Synonym
Above-knee amputation, Transfemoral amputation

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: Niet gefinancierd

Intervention

Keyword: Implant, Randomized, Transfemoral amputation

Outcome measures

Primary outcome

- Pain level as rated on a VAS scale

- Distance/speed of walking assessed using the 6 Minutes Walking Test

- Patient's quality of life assessed using the Prosthesis Evaluation Questionnaire and the SF-36

- Implant failure assessed using the number of Serious Adverse Events

Secondary outcome

- Bone mineral density assessed using bone densitometry

- Hours of daily prosthetic use assessed using Houghton scale and a diary to keep track of prosthetic usage

- Oxygen consumption during walking assessed using aerobic ergometry

- Timed up and go test

- Use of walking aids

- Hip range of motion assessed using a goniometer

- Number and type of skin and stump problems

- Spatiotemporal, kinematic, and kinetic variables of walking assessed using an opto-electronic gait analysis system

- Muscle activation patterns assessed using electromyography

Study description

Background summary

After a conventional transfemoral amputation, the residual leg cannot be distally loaded as this will create an pressure ulcer due to a high load of the residual femur on the soft tissue of the stump. This means that the exerted load on the leg during walking needs to be transferred to other body parts. Usually this load is transferred to the ischial bones through the stump socket. This, however, has some disadvantages. Transferring the load to the ischial bones requires a long stump socket which can be uncomfortable during sitting down. In addition, it can pinch the skin during walking which can be highly uncomfortable. The Spanish company Tequir, developed a possible solution for these problems. They developped the Keep Walking Femoral Implant. Placing this implant creates a stump that can be partially distally loaded, which decreases the need to transfer loading forces to other body parts. A clinical study that was performed as part of the CE-marking process showed that placing the Keep Walking Femoral Implant increased walking function and decreased pain level. The next step is to investigate whether these results hold up in a larger European study.

Study objective

The primary objective is to obtain post-market clinical data according to the requirements of the MEDDEV 2.21/2 in order to fulfil 18 post-market surveillance (PMS) obligations according to Section 3.1 of Annex II, 19 Section 3 of Annex IV, Section 3 of Annex V, Section 3.1 of Annex VI or Section 4 20 of Annex VII of the Medical Devices Directive (94/42/EEC).

Study design

The study is designed as an international multicenter randomized clinical study.

Intervention

For in the intervention group the intervention consists of placing the Keep Walking Femoral Implant.
There is no intervention for the control group.

Study burden and risks

The burden and risk associated with participation are mainly limited to the risk that is associated with the placement of the Keep Walking Femoral Implant. In the initial study, complications led to the extraction of the Keep Walking Femoral Implant in 6 of the 29 subjects. By applying stricter inclusion criteria, it is thought that this risk is descreased in the current study.
The tests that we will apply in this research are comparable to activities of

daily living and we therefore believe that this burden is relatively low. There is no added risk associated with the measurements.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Have been indicated for a transfemoral amputation due to traumatic, vascular, or oncologic aetiology;
- In case of vascular aetiology: presence of femoral pulse with no significant stenosis (percentage of stenosis lower than 60%) and PPCI hemodynamic index below 0.25;
- Have the ability to bear weight on the contralateral (intact) leg during at least 10 seconds, with or without using technical aids;
- Have functional walking ability between 8-12 weeks prior to the amputation, with or without technical aids;

- Have a residual femur length of at least 14 centimetre measured from the greater trochanter.

Exclusion criteria

Absolute contraindications
- Age <18 years
- Active neoplasia pathology
- Currently undergoing chemotherapy treatment
- Currently using immunosuppressant
- Sepsis or active infection
- Residual length of the femur less than 12 cm measured from the greater trochanter
- Pregnancy
- Alcohol or drug addiction
- Alterations of the central nervous system (CNS): dementia, cerebral tumours, degenerative pathology etc.
- Patient that does not consent to participation in the study
- Psychiatric disorders
- Allergy to any of the components of the implant;Relative contraindications
- Severe osteopenia or osteoporosis (cortical bone thickness less than 3 mm)
- Previous infection of the stump
- Deformity in hip flexion greater than 300
- Residual length of the femur between 12 and 14 cm measured from the greater trochanter.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2018

Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Keep Walking Femoral Implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-12-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-10-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL65121.044.18
Other	Nog niet bekend