Bone remodeling in transfemoral amputees with a bone-anchored prosthesis after transfemoral amputation.

Published: 29-06-2020
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The main objective of the study is to explore the bone remodeling in order to examine long-term stability of the implant after 10 years follow-up.

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

Summary

ID

NL-OMON49955

Source
ToetsingOnline

Brief title
BONEKLICK

Condition

- Bone disorders (excl congenital and fractures)

Synonym
bone resorption, cortical thinning

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,R0004031 (H2020

780871 MyLeg)

Intervention

Keyword: amputation, bone remodeling, bone-anchored prosthesis, osseointegration

Outcome measures

Primary outcome

The main study parameter is changes in bone remodelling in terms of bone

density, cortical thickness and distal bone resorption measured with DXA scans

and conventional radiographs.

Secondary outcome

-

Study description

Background summary

A Bone-Anchored Prosthesis (BAP) is an alternative solution to a socket-suspended prosthesis (SSP) of upper-leg prosthesis. It allows overcoming soft tissue problems and offers better control over the external prosthetic system by direct attachment to the femoral remnant by means of an osseointegrated implant (OI). By doing so, the BAP is expected to promote increased loading of the bone and its remodelling. In an earlier study we presented the first results of a cohort after two years of follow-up.

Study objective

The main objective of the study is to explore the bone remodeling in order to examine long-term stability of the implant after 10 years follow-up.

Study design

The study will be a prospective cohort study.

Study burden and risks

No special risks are involved in the study. The radiological examination with

DXA scanner is an approved medical standard.
The most benefits will be present for the future patients, whose treatment will be possibly improved by the gained knowledge.

Contacts

Public
Selecteer

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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

participation in 2010-099

Exclusion criteria

Explantation of the osseointegration implant

Removal of the outer part or distal part of the intramedullary stem with closure of the stump

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-11-2020
Enrollment:	27
Type:	Actual

Ethics review

Approved WMO Date:	29-06-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-08-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-09-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-01-2023

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL73215.091.20

Study results

Date completed:	13-01-2023
Actual enrolment:	18