The Dutch press-fit bone-anchored prosthesis cohort study

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Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28540

Bron
NTR

Aandoening

Artificial limbs, Osseointegration, Quality of life, Function level, Activity level, Participation level

Ondersteuning

Primaire sponsor: Radboud university medical center
Overige ondersteuning: Radboud university medical centre

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameters are:
a) function level defined as kinematics in coronal plane (degrees), hip abductor strength (Nm/kg), prosthetic use (Q-TFA PUS: 0-100), back pain ('no', 'episodes', 'yes'), and stump pain (NRS: 0-10);

b) activity level defined as mobility level (MFC-level: 0-4; SIGAM WAP mobility score: A-F; use of aids in daily life: 'wheelchair-bound', 'walking frame / rollator', 'two crutches / canes', 'one crutch / cane', 'none'; Timed up and go: seconds) and walking ability (6-minute walking test: meters; walking distance in daily life: meters);
c) HRQoL (Q-TFA GS: 0-100);
d) satisfaction level defined as prosthesis comfort (0-10) and global perceived effect ('extremely poor', 'poor', 'average', 'good' or 'extremely good').

Toelichting onderzoek

Achtergrond van het onderzoek

Background: Patients with a lower extremity amputation frequently suffer from socket-related problems which seriously limit prosthesis use, and hence activity level and health-related quality of life (HRQoL). An additional problem is gait asymmetries which may account for back pain. Bone-anchored prostheses (BAPs) are a possible solution for socket-related problems, however knowledge concerning the level of function, activity and HRQoL after surgery is limited. There are two types of BAPs: screw BAP and press-fit BAP.

The aim of this study is threefold, to: a) describe changes in the level of function, activity, HRQoL and satisfaction over time compared to baseline before surgery; b) examine potential predictors for the change of prosthetic use, walking ability, prosthesis comfort and HRQoL over time, and the level of post-operative stump pain; c) examine potential mechanisms for change of back pain over time by identifying predictors, moderators and mediators.

Methods/design: This is a prospective before-after study with multiple follow-ups in all consecutive adults with a lower extremity amputation who received a press-fit BAP in May 2014 or later. Patients with socket-related problems and trauma, tumour resection or stable vascular disease as cause of primary amputation will be included. Severe cognitive or psychiatric disorders are an exclusion criteria. Follow-ups are planned at six-months, one-, two- and five-years after BAP surgery. The main study parameters are: a) function level defined as kinematics in coronal plane, hip abductor strength, prosthetic use, back pain, and stump pain; b) activity level defined as mobility level and walking ability; c) HRQoL; d) satisfaction level defined as prosthesis comfort and global perceived effect. Time trends of the continuous outcomes and of one dichotomized outcome (back pain) will be analysed using generalized estimating equations (GEE). Multivariate GEE will be used to identify potential predictors for change of gait quality, prosthetic use, walking ability, HRQoL and prosthesis comfort, and for the level of post-operative stump pain. Further potential mechanisms for change of back pain will be explored using gait quality as potential determinant and stump pain (moderator) and hip abductor strength (mediator).

Discussion: This study potentially will identify independent variables for clinical relevant outcome measures.

Doel van het onderzoek

The primary aim is threefold:

1) To describe the change in the level of function, activity, HRQoL and satisfaction in patients with a lower extremity amputation after receiving a press-fit BAP at short-term (six-months and one-year), mid-term (two-years) and long-term (five-years) in comparison to the baseline. We hypothesise that the following outcomes will improve over time: gait quality, hip abductor strength prosthetic use, mobility level, walking ability and health-related quality of life (HRQoL). Further, we assume that back pain will decrease over time.

2) To examine predictors for the change of gait quality, prosthetic use, walking ability, HRQoL and prosthesis comfort over time. These selected outcomes of interest are the main reason for patients to choose for a BAP in our clinic, therefore we aim to explore potential predictors for these outcomes. Candidate predictors are age, body mass index, time from primary amputation to inclusion, cause of amputation, level of amputation, length residual limb, baseline hip abductor strength, baseline prosthetic use, back pain at follow-ups, stump pain at follow-ups, baseline walking ability, baseline prosthesis comfort and the baseline values of the outcomes of interest.

3) To examine predictors for the level of stump pain at short-term, mid-term and long-term follow-ups. Candidate predictors are time from primary amputation to inclusion, level of amputation, length residual limb, baseline hip abductor strength, baseline prosthetic use, basline mobility level and basline walking ability.

The secondary aim is to examine potential mechanisms for change of back pain at short-term, mid-term and long-term. We assume that gait quality will be a possible determinant for change of back pain. Further we hypothesise that stump pain will act as moderator and hip abductor strength will act as mediator.

Onderzoeksopzet

All primary outcome are measured at baseline (preoperatively) and at six-months, one-, two- and five-years after surgery with exception of stump pain and global perceived effect which are only assessed postoperatively.

Onderzoeksproduct en/of interventie

Press-fit bone-anchored prosthesis surgery in combination with rehabilitation

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All consecutive patients in our centre (Radboud university medical centre) who underwent BAP surgery after May 2014 were eligible for this study. All assessments are part of usual care.

Patients are eligible for press-fit BAP surgery if: a) they are adults with a lower extremity amputation suffering from socket-related problems contributing to limited prosthetic use; b) cause of primary amputation is a trauma, tumour resection or stable vascular disease.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria for surgery are a medical history of severe cognitive or psychiatric disorders.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	08-05-2014
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4912
NTR-old	NTR5776
Ander register	Ethics Committees of Radboud university medical center : 2014/196

Resultaten