Long term follow up after rotationplasty

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A better quality of life, function and energy expenditure within the rotationplasty patients compared to the patients with a above knee amputation.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25651

Bron
Nationaal Trial Register

Verkorte titel
Rotationplasty

Aandoening

Osteosarcoma, Ewingsarcoma, Chondrosarcoma, Giant cell tumor, Synoviosarcoma, Proximal focal femoral deficiency

Ondersteuning

Primaire sponsor: St. Lodewijk- de Kort and the Dpt. of Orthopedic surgery Amsterdam UMC (AMC)
Overige ondersteuning: St. Lodewijk- de Kort and Dpt. of Orthopedic surgery Amsterdam UMC (AMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To asses health-related quality of life and functional outcome after long-term follow up, in patients treated with a rotationplasty for primary malignant bone tumours or PFFD compared

to above-knee amputation means for similar indications.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Rotationplasty is an alternative to above knee amputations or endoprosthesis for mainly oncologic indications. Major advances of rotationplasty are preservation of knee function, wide surgical oncological margins with a relatively low complication and additional surgery rate. The procedure consists of resection of a tumor about the knee, whilst preserving neurovascular structures, thereby enabling rotation and re-attachment of the distal leg to the proximal portion.
Objective: To assess the quality of life and functional outcome of rotationplasty after long-term follow-up.
Study design: Cross-sectional follow-up study.
Study population: Patients treated with a rotationplasty for primary malignant bone tumours or proximal femoral focal deficiency (PFFD) between 1980-2005. Results will be compared with patients after an above knee amputation (AKA) for similar indications, during the same period (control group).

Doel van het onderzoek

A better quality of life, function and energy expenditure within the rotationplasty patients compared to the patients with a above knee amputation.

Onderzoeksopzet

-17/09/2020 start data collection, first patient visit at the Amsterdam UMC (location AMC). The participants will visit the outpatient clinic to undergo a physical examination (hips, knee- and ankle function) and get plain radiographs of the formal ankle joint, now functioning as a knee (including the contralateral ankle to compare with) and of the pelvis (to compare osteoarthritis development of both hips). If they did not fill out computer based questionnaires at home, they can to do that during their one time visit at the outpatient clinic. This part of the study will be performed at the department of orthopaedic surgery of the AMC in Amsterdam, the Netherlands. When possible during the same visit, patients undergo a 3D gait analysis and 6-minute walking energy cost test performed at the department of rehabilitation of the AMC in Amsterdam, the Netherlands.
-17/09/2020 start collection patient questionnaires
The participants can either fill out the self-reported questionnaires (SF 36, TESS, PEQ, VAS, AOS, FAOS and social-/ prosthesis related questions) at home through internet (using Castor Electronic Data Capture) or on paper at the outpatient clinic.

After this date approximately two patients a week will visit the outpatients clinic.

Onderzoeksproduct en/of interventie

Health-related quality of life (HRQoL) and functional outcome after long-term follow up, in patients treated with a rotationplasty for primary malignant bone tumors or PFFD compared to AKA for similar indications.
1. Self-reported health-related quality of life (Qol), assessed with the 36-item Short Form Health Survey (SF-36).
2. Self-reported activity limitations, assessed with the Toronto Extremity Salvage Score (TESS) measuring functionality, and parts of the Prosthesis Evaluation Questionnaire (PEQ) measuring satisfaction with the prosthetic device. To objectify activity limitations, gait biomechanics, and walking speed, and energy cost, are assessed with 3D gait analysis and a 6-minute walk test, respectively.
3. Impairments in ankle (now knee) joint function will be measured with the Ankle Osteoarthritis Score (AOS), Foot and Ankle Outcome Score (FAOS)and Visual Analogue Score (VAS). Additional physical examination will focus on knee angulation (genua valga/ vara) or foot defects, impingement, range of motion (American Orthopaedic Foot and Ankle Society (AOFAS) score12-14) and muscle strength (Medical Research Council (MRC)). To objectify joint rejections osteoarthritis on plain radiographs are evaluated, using individual radiographic features.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

· Treated with a rotationplasty for primary malignant bone tumours or PFFD at the AMC or at the OLVG in Amsterdam between 1980-2005.
· Being able to visit the AMC in Amsterdam once or twice.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

· To perform the walking energy cost measurements, patients need to walk 6 minutes. If they cannot maintain 6 minutes of walking, they are only excluded for that part of the study.
· Patients who cannot read and/ or write Dutch cannot participate the study.
· Patients with contra-indications for radiographs will be exempted to this part of the study.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	07-09-2020
Soort:	Eerste indiening

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	NL8899
Ander register	Amsterdam UMC (AMC) : AMC2020_018

Resultaten