Long term follow up after rotationplasty

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25651

Source
Nationaal Trial Register

Brief title
Rotationplasty

Health condition

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

Sponsors and support

Primary sponsor: St. Lodewijk- de Kort and the Dpt. of Orthopedic surgery Amsterdam UMC (AMC)
Source(s) of monetary or material Support: St. Lodewijk- de Kort and Dpt. of Orthopedic surgery Amsterdam UMC (AMC)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

· To evaluate factors affecting health-related quality of life, occupation and sport activities with regard to the performed rotationplasty.
· To measure self-reported activity limitations of these patients by questionnaire's and satisfaction with their external prosthesis. And to further objectify activity limitations after rotationplasty, as measured by gait biomechanics, walking speed and walking energy cost.
· Furthermore, impairments will be revealed by physical examination of hips, knee and ankles objectified by development of osteoarthritis on plain radiographs.

Study description

Background summary

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).

Study objective

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

Study design

-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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

· 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.

Exclusion criteria

· 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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2020
Enrollment:	70
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	07-09-2020
Application type:	First submission

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
NTR-new	NL8899
Other	Amsterdam UMC (AMC) : AMC2020_018

Study results