Gait symmetry of patients with an endoprosthetic reconstruction of the knee joint after bone tumour resection.

Published: 24-10-2019
Last updated: 10-04-2024

The primary goal of this study is to describe possible causes of gait asymmetry in patients with an endoprosthetic reconstruction of the knee joint due to a bone tumour. Therefore, the assumed gait asymmetry is first verified (part A). Subsequently…

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

Summary

ID

NL-OMON52588

Source
ToetsingOnline

Brief title
Gait symmetry with a knee endoprosthesis after tumour resection

Condition

- Bone disorders (excl congenital and fractures)
- Skeletal neoplasms malignant and unspecified
- Bone and joint therapeutic procedures

Synonym
bone cancer, bone tumour

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bone, Endoprosthesis, Gait, Tumour

Outcome measures

Primary outcome

Measurements are performed in two gait labs. Part of this amendment is the addition of a second gait lab.

Gait Laboratory 1 is the Technology in Motion (TIM) lab at the LUMC. We use the interactive walkway. The interactive walkway makes it possible to record movements without sensors.

Gait laboratory 2 is the movement lab for rehabilitation medicine at the LUMC. The M-Gait treadmill, a treadmill with multiple calibrated camera setup and bilateral continuous ground reaction force measurement, was introduced in 2022.

The participant first walks in lab 1 and then in lab 2.

Measurements

- Step time (s) during unperturbed comfortable walking for the affected leg and the unaffected leg measured with the Interactive Walkway. Step time is the time interval between initial contact of one leg to the consecutive initial contact of the contralateral leg;
- Interlimb step time difference (s) to quantify for (a)symmetry;
- Patient reported outcome scores (PROM's) for pain, fear (kinesiophobia) and health using a numeric rating scale (NRS) administered before gait analysis.

For measurements on the treadmill, the participant will be secured in a CE-approved harness that is secured to the ceiling with ropes under dynamic pretension. For measurements with the M-Gait the subjects will walk on the treadmill for one-and-a-half minute twice: once with the mean walking velocity measured earlier with the IWW, in order to maximize the comparability with data obtained with the IWW, and once using self-paced mode, where the treadmill speed is automatically adapted to the patients walking speed. For both measurements, the patient will be able to get familiar with walking on the treadmill for the first 30 seconds and only the last minute of walking will be recorded and used for analysis.

Secondary outcome

- Toronto Extremity Salvage Score (TESS), lower extremity version: a validated questionnaire to assess patient-reported physical outcome;
- Pedometer-assessed (health app, mobile phone) steps per day, if available, of the last week for assessing the daily physical activity;
- Other walking data recorded in the TIM-lab can be used for possible sub analyses: centre of body mass, gait speed, step width, step length, stride time, turning time, stride length, cadence.

Study description

Background summary

The life expectancy for patients with bone tumours is increasing and therefore long-term functioning has become more important. When bone tumours are located around the knee, a custom-made tumour prosthesis of the knee joint is often implanted after the tumour is resected. It is likely that patients use the

affected leg and the unaffected leg asymmetrically during walking due to e.g. anatomical changes, neural damage, pain and fear. This leads to a less efficient walking pattern. The relation of affected ambulance with these underlying causes are not yet known, but essential for tailored therapy (e.g. physical-, psychological-, rehabilitation therapy, pain management). We hypothesize that patients after endoprosthetic reconstruction show asymmetrical ambulance, resulting in a longer step time for the affected leg compared to the unaffected leg. This asymmetry is assumed to relate to pain, fear and health scores.

Study objective

The primary goal of this study is to describe possible causes of gait asymmetry in patients with an endoprosthetic reconstruction of the knee joint due to a bone tumour. Therefore, the assumed gait asymmetry is first verified (part A). Subsequently, gait asymmetry is related to pain-, fear- and general health, as possible causes (part B). Secondarily, gait asymmetry is related to functional outcome measures in order to see whether gait asymmetry affects daily functioning.

Study design

This study is an observational single-centre cross-sectional cohort study, that takes place in two parts. Depending on the interim analysis after part A, we will continue if sufficient asymmetry is observed. If gait is symmetrical, the study will be terminated.

Study burden and risks

This visit will take approximately 30 minutes. Motion registration will be done in a quick and patient-friendly manner. Movement data are obtained by multiple Microsoft Kinect sensors that do not require markers to be attached to the body of to the subjects' bodies. Subjects will not personally benefit from participation in this study.

In such a movement analysis, however, a fall risk is equated with the risk of falling during normal walking. On the treadmill, extra protection is provided with a harness while running.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Tumour resection and a reconstruction of the knee joint with a MUTARS® system (Modular Universal Tumour and Revision System) in the LUMC during the previous 10 years (2008-2018) due to a primary bone tumour around the knee (distal femur or proximal tibia); Tumour resection and reconstructive surgery is at least 1 year ago; One unaffected (healthy) leg; Normal or corrected to normal vision; At least 18 years old at time of inclusion; Signed informed consent form.

Exclusion criteria

Major revision surgery (e.g. total replacement of the prosthesis with reattaching muscles) in the last 1 year; Minor revision surgery (e.g. replacement of a small part of the prosthesis without reattaching muscles) in the last 3 months; Endoprosthetic failure; Comorbidities interfering with gait function Inability to comply with the assessment in the TIM laboratory; Inability to walk independently.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2019
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Interactive Walkway: Microsoft Kinect V2 sensors + HD projector + computers
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	24-10-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	16-02-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	27-05-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL69691.058.19