TLEMsafe: Improving safety and predictability of complex musculo-skeletal surgery using a patient-specific navigation system. Part IIa: validation with sarcoma patients pre and post OR.

Published: 03-05-2012
Last updated: 26-04-2024

To create and validate patient-specific post-OR M-S models of the lower limb of sarcoma patients. The primary goal is to see if the model can accurately predict whether a patient can or cannot walk after surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue neoplasms
Study type	Observational invasive

Summary

ID

NL-OMON37531

Source
ToetsingOnline

Brief title
TLEMsafe part IIa: sarcoma patients.

Condition

- Musculoskeletal and connective tissue neoplasms

Synonym
(specific type of) cancer., Sarcoma

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Europese Commissie

Intervention

Keyword: musculo-skeletal modelling, orthopaedic surgery, patient-specific, surgical navigation

Outcome measures

Primary outcome

The main study parameters are 1) changes in anatomical musculo-skeletal parameters pre- and post-OR, and 2) the amount of difference in spatiotemporal, kinematic and kinetic parameters during basic activities of daily living between model outcome and actual measurement (9 months post-OR). The anatomical parameters consist of muscle attachment points, muscle wrapping contours, muscle volumes, bony landmarks, tendon lengths and physiological cross-sectional areas of muscles. The spatiotemporal, kinematic and kinetic parameters include walking speed, stride length, cadence, hip range of motion, maximal hip flexion/extension, hip power generation/absorption, and hip flexion moment during various activities of daily living.

Secondary outcome

not applicable.

Study description

Background summary

In the treatment of sarcoma of the lower limb, whether it be osteosarcoma, Ewing sarcoma or soft tissue sarcoma, the surgeon has to make many important decisions. The first is whether to amputate or to attempt to preserve the limb. With increased surgical expertise and improved diagnostic imaging techniques, amputation can nowadays be avoided for the vast majority of patients. These patients undergo limb-saving surgery. In this procedure, the surgeon always excises the tumor with a margin around it to prevent local recurrences. In spite of all the advancements made in the surgical treatment of sarcoma, the consequences of a specific excision margin on post-OR functionality for a specific patient is sometimes unknown to the surgeon. In the case of an osteosarcoma, the surgeon removes the affected part of the bone including a margin of surrounding soft tissue after which a bone-replacing prosthesis has to be placed. The consequences of this extensive surgery on post-OR functionality are hard to predict. To improve the predictability of limb-saving surgery, the surgeon would benefit greatly from a pre-planning system that could show him the effects of several surgical scenarios on post-OR functionality. The TLEMsafe project will create such a system. To this end, we will use a state-of-the-art musculo-skeletal (M-S) model of the lower limb which has recently been developed. In this model, the performance of basic activities of daily living after surgery can be simulated. In order to simulate activities of daily living after surgery in an accurate manner, the model first has to be made patient-specific and undergo rigorous validation. In the first part of the project (CMO 2011/011), healthy-subject-specific M-S models have been created, which are currently being validated. In the present phase of the project, we will create and validate patient-specific post-OR M-S models of sarcoma patients. This is a crucial step towards the construction of a reliable surgical pre-planning system.

Study objective

To create and validate patient-specific post-OR M-S models of the lower limb of sarcoma patients. The primary goal is to see if the model can accurately predict whether a patient can or cannot walk after surgery.

Study design

Observational prospective cohort study.

Study burden and risks

Participation entails an MRI scan pre-OR and 6-9 months post-OR, and a session 6-9 months post-OR during which the patient performs basic activities of daily living. Each MRI scan takes about 45 minutes. The scans are made exclusively of the lower limb. The activities of daily living that patients have to perform 6-9 months post-OR take place in the motion laboratory of the department of Rehabilitation. This session takes three to four hours to complete. In this

session, 3-D kinematics, ground reaction forces measurements and electromyography will be employed to measure the patient*s post-OR functionality during activities of daily living such as walking, getting up from a chair, stepping over an obstacle, and maintaining balance while standing on a moveable platform.

The MRI scans are painless and not dangerous. The largest burden of participation lies in the fact that patients have to be informed about the study, asked for participation, and undergo an extra pre-OR MRI scan in the month between the first outpatient visit to the surgeon and the surgery itself. To lower this burden, the scan will be scheduled as much as possible on a day that the patient is already at the RUMC for other treatment-related visits. The post-OR MRI scan and the motion laboratory session will also be planned on the same day as treatment-related visit days as much as possible. All of the measurements in the motion laboratory are regularly performed in this laboratory and are non-invasive and painless. If a patient anticipates or experiences pain during any of the exercises, that exercise will be skipped.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 2
6525 CG Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 2
6525 CG Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients must have a soft-tissue, Ewing or osteosarcoma in the upper leg or pelvis region, be between 18-60 years of age, and have a body mass index between 17-30.

Exclusion criteria

- Other pre-existing deformities of the M-S system such as scoliosis and hip dysplasia.
- Neurological diseases that affect the functioning of the M-S system.
- Use of medication that affects the functioning or the neurological control of the M-S system.
- Having had major injury or orthopedic surgery of the lower limb at an earlier time in life, from which full recovery was never reached.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-02-2013
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	03-05-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-06-2012
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	NL39833.091.12