Twente Lower Extremity Model safe: Improving safety and predictability of complex musculo-skeletal surgery using a patient-specific navigation system.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Observational invasive

Summary

ID

NL-OMON36523

Source
ToetsingOnline

Brief title
TLEMsafe

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

Synonym
None, not in this application: hip dysplasia, osteosarcoma), this research involves healthy subjects. (at a later stage

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

Our primary outcomes are anatomical and physiological musculo-skeletal parameters. The anatomical parameters are extracted from MRI scans. They consist of muscle attachment points, muscle wrapping contours, muscle volumes, bony landmarks, tendon lengths and physiological cross-sectional areas of muscles. Physiological parameters are measured from kinematic and ground reaction force data, surface electromyography, oxygen measurements, and PET during various activities. They consist of torque around the hips, knees and ankle joints, joint compression forces, muscle activition timing, muscle force production and muscle energy consumption. The latter two are particularly important to validate because they are primary outcomes of the M-S models. Muscle energy consumption will be measured with PET.

Secondary outcome

Not applicable.

Study description

Background summary

A state-of-the-art musculo-skeletal (M-S) model of the lower extremity (TLEM - the Twente Lower Extremity Model) has recently been developed. The ability to perform activities of daily living after surgery can be simulated in the model. The goal of the TLEMsafe project is to use this model to improve the safety and predictability of M-S surgery. The model will have to be made patient-specific and undergo rigorous validation to achieve this goal. In this first part (the validation part) of the project, healthy-subject-specific M-S models will be created from parameterization of MRI scans. The models will then be validated by comparing model-simulated predictions about the performance of maximum voluntary contractions (MVCs) and basic activities of daily living to real-life measurement data (e.g. 3-D kinematics, ground reaction forces, muscle activation timing, muscle energy consumption) of such activities as they are performed by subjects in the motion laboratory. We will also use the PET scans to develop a new method for validation of musculo-skeletal models.

Study objective

Primary objective: To create and validate healthy-subject-specific musculo-skeletal models of the lower extremity. We will also develop a new method using the Positron Emission Tomography (PET) technique that can be used to validate musculo-skeletal models in general. The PET scans thus serve two purposes. They offer us energy consumption data with which we can validate our models, but also serve as a basis for the development of a new method that can be used to validate musculo-skeletal models in general. Such a method does not yet exist in the literature. Therefore, the PET scans offer interesting publication opportunities.

Study design

Observational prospective cohort study.

Study burden and risks

Participation entails three measurement sessions at the Radboud University Nijmegen Medical Center and the Sports Medical Center of the Sint Maartenskliniek.

Session one takes place at the department of Radiology and the department of Nuclear Medicine. It consists of a magnetic resonance imaging (MRI) scan, a positron emission tomography/computed tomography (PET/CT) scan and an oxygen consumption measurement during walking. Both the MRI scan and the PET/CT scan are made exclusively of the lower extremity. To correct the PET scan images for attenuation by the body, a low-dose attenuation CT scan will be made during the PET scan. Subjects will be injected with 50 MBq [18F]Fluorodeoxyglucose (FDG). The combined PET/CT scan results in an effective dose of about 3 mSv. This session takes approximately four hours to complete.

Session two takes place in the motion laboratory of the department of Rehabilitation. In session two, 3-D kinematics, ground reaction forces, electromyography and ultrasound scans will be employed to measure physiological parameters and task performance during MVCs and basic activities of daily living such as walking, getting up from and sitting down on a chair, and stepping over an obstacle. All of these measurements are very common in this laboratory and are painless and non-invasive. This session takes approximately three hours to complete.

In session three, subjects perform isokinetic and isometric contractions of the joints of the lower extremity. Specifically, flexion and extension of the hip, knee and ankle and abduction of the hip will be tested. The setup that will be used to measure the isokinetic and isometric contractions is a Humac Norm, which is a commercially available apparatus designed specifically for performing these measurements. It has already been used for many other studies in the literature without the occurrence of adverse events.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy, age 18-60, body mass index 17-30.

Exclusion criteria

Deformities of the musculo-skeletal system such as scoliosis and hip dysplasia.
Use of medication that affects the functioning or the neurological control of the musculo-skeletal system.
Having had major injury or orthopedic surgery of the lower extremity at any time during life.
History of ailment related to carbohydrate metabolism, or to cardiac or muscular disease.
Being pregnant or having the intention to become pregnant during the course of the study.

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):	28-07-2011
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	26-07-2011
Application type:	First submission
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	NL35063.091.11

Study results

Date completed:	26-01-2012
Actual enrolment:	10