Validity and reproducibility of ambulatory measurement of the frontal knee moment in patients with osteoarthritis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32213

Source
ToetsingOnline

Brief title
Frontal knee moment in OA patients (AmbuKOA)

Condition

- Joint disorders

Synonym
knee joint disease, Osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Het onderzoek is deel van het FreeMotion project;gefinancieerd door het Ministerie van Economische Zaken en Senter Novem

Intervention

Keyword: Ambulatory measurement system, Knee Moment, Osteoarthritis

Outcome measures

Primary outcome

The main outcome measure of the study is the difference in frontal knee moment,

measured with the ambulatory system versus the reference system.

Secondary outcome

Secondary study parameter is the knee angle.

Study description

Background summary

Osteoarthritis (OA) of the knee is an age-related degenerative joint disease. It affects a substantial part of the elderly population, causing limitations in daily physical functioning. The netto frontal knee moment (i,e, the external adduction/abduction moment) is directly related to the load in the knee. Its value during gait is often used as an identifier of disease severity and evaluation of treatment. In a research environment it is usually estimated from using force plates and optoelectronic measurements in a gait laboratory. However, such specialized equipment limits clinical use of this method. Alternatively, an ambulatory measurement system can be used, based on instrumented force shoes (IFS) and inertial and magnetic sensors (IMS). Such systems are increasingly relevant in clinical practice and need to be validated.

Study objective

The aim of the study is to evaluate the validity and reproducibility of the ambulatory system, containing IFS*s and IMS*s, with respect to a reference system, to measure the frontal knee moment during gait in patients with osteoarthritis. As a reference, a force plate and optoelectronic marker system will be used.

Study design

This is a observational cross-sectional study. Measurements will be performed in the gait laboratory of the VU University Medical Center in Amsterdam. 20 patients will be measured in a first session using the ambulant and the reference system, as well as force shoes and normal shoes, to investigate the validity; 10 patients will be measured a second time to determine reproducibility.

Study burden and risks

Patients will be asked to walk a 10m walkway at self-selected speed, wearing IFS and normal shoes, IMS and marker clusters attached to the segments of the lower extremities. The measurements are non-invasive. Markers, sensors and cables may somewhat increase the burden during the measurements compared to normal walking. During walking, pain and fatigue could occur, however, the risk of pain will be minimal. Patients can quite the measurements if pain will occur. The practical relevance of this study is that validation of the ambulatory system in a clinical situation may help to introduce such systems in clinical practice. in order to provide more insight in the frontal knee moment in OA patients, and to be used in evaluation of treatment of OA.

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

Diagnose of knee osteoarthritis (uni- or bilateral)
Between 40 and 75 years of age

Exclusion criteria

Poly-arthritis,
Presence of rheumatoid arthritis or other systemic inflammatory arthropathy,
Knee surgery within the last twelve months or a history of knee arthroplastic surgery,
Inability to understand the Dutch language.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-09-2008
Enrollment:	20

Type:	Actual

Ethics review

Approved WMO Date:	14-07-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL23052.029.08