Knee joint (in)stability in patients with knee osteoarthritis*

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The objective is to develop a reliable and concurrent valid KneeGSN that expresses the knee joint (in)stability during gait in KOA patients.

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

Summary

ID

NL-OMON47889

Source
ToetsingOnline

Brief title
Stability in Osteoarthritis (STOA)

Condition

- Joint disorders

Synonym
osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Reumafonds

Intervention

Keyword: Gait, Knee, Osteoarthritis, Stability

Outcome measures

Primary outcome

The primary outcomes of the study are the responses of the gait kinematics, gait kinetics and EMG signals (of the main muscles spanning the knee joint) during and after mechanical perturbations.The responses of the subjects forms the basis for the development of the dynamic stability measure (GSN).

Secondary outcome

Secondary outcomes of the study are self-reported knee joint instability (Knee Outcome Survey (KOS) and Knee disability and Osteoarthritis Outcome Score (KOOS)), postural balance, self-reported functional ability (Western Ontario and McMaster Universities Arthritis Index (WOMAC), functional performance tests (Get Up and Go test (GUG), 10-meter walk test), knee joint proprioception, Varus * Valgus laxity, muscle strength (HUMAC NORM isokinetic knee test) and disease severity (Kellgren and Lawrence grade (K&L)).

Study description

Background summary

Knee osteoarthritis (KOA) is a common disease in elderly. Osteoarthritis involves progressive degeneration of the cartilage, which leads to immobility and pain for the patient. Along with this, a large part of the patients report knee joint instability during daily activities (like walking). Patients perceive knee joint instability as a sensation of buckling, shifting or giving away of the knee joint. Studies suggest that knee joint instability could be a key concept in explaining initiation and progression of KOA. The lack of trust in the knee joint may result in a gait compensation mechanism, that alters the knee mechanics which accelerates further cartilage wear. Currently the concept of knee joint instability is based on subjective patient reported outcome; or on static, passive measurements of the laxity of the knee or on postural balance tests. None of these methods objectively measures the dynamic

instability of the knee joint. A quantitative measure to express knee joint instability during dynamic tasks (mainly gait) would be helpful to objectively diagnose instability; to get a better understanding of the mechanisms of instability in KOA; and to optimize therapy aiming to improve knee joint stability in patients. Recent developments in experimental gait analysis labs and the robotic field made it possible to create a measure such as the Gait Sensitivity Norm (GSN) based on small perturbations during gait. The GSN can use one or several parameters (gait or knee) as an input. Results of a pilot study in healthy young subjects illustrate the feasibility of the development of such a quantitative measure for stability in the knee.

Study objective

The objective is to develop a reliable and concurrent valid KneeGSN that expresses the knee joint (in)stability during gait in KOA patients.

Study design

An explorative observational study will be performed with in the first study (A) 20 KOA patients with self-reported instability, 20 KOA patients without self-reported instability and 20 healthy controls. Dynamic knee joint stability will be assessed by exposing subjects to perturbations while walking on an instrumented treadmill in a virtual reality environment (GRAIL system). Gait kinetics, gait kinematics and electromyography (EMG) of the lower extremity will be measured to capture the responses of the subjects to these perturbations. The differences in responses between the groups form the basis for the KneeGSN. Reliability and concurrent validity of the measure of dynamic knee joint instability will be evaluated in a second study (B) with 20 KOA patients (14 with self-reported instability). In study B two measurements will be performed (a week apart) to test the reliability. Study A will only be one measurement.

Study burden and risks

The study has a low burden on the study group, because no intervention will be tested and it involves a common motor task (walking). The risk associated with this study is small and could only be caused by the instrumented treadmill that induces small perturbations on the subject. However, these perturbations are performed in a controlled environment with safety equipment such as a harness to prevent falling. Other studies which made use of these type of perturbations were already approved by the METC. There is no direct benefit for the patient. However, results of this study could provide better insight in the disease and enables a stronger base (quantitative assessment) for intervention studies aiming to stabilize the knee (braces, muscle strengthening).

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

In order to be eligible to participate the study, a knee osteoarthitis (KOA) subject must meet all of the following criteria:
- Unilateral or bilateral diagnosis of the KOA according to the American college of Rheumatology (ACR) criteria. ACR criteria are age over 50 years, morning stiffness less than 30 minutes, crepitus on active motion, bony tenderness or absence of palpable warmth of synovium.
- Able to walk for 5 minutes without stopping.
- A maximal score of 7 on the numeric scale (NRS) for pain intensity during the past two weeks.
- Body mass index (BMI) between 20 and 35 kg/m2.;The KOA subjects will be assigned to the KOA-I group (group with unstable knees) based on the following criterion:
- Have had the perception of an episode of buckling, shifting or giving way of the knee in the

past 4 weeks based on questionnaire (KOS-ADLS).;The KOA subject will be assigned to the KOA-S group (group with stable knees) based on the following criterion:
- Have had no perception of an episode of buckling, shifting or giving way of the knee in the past 3 months on questionnaire (KOS-ADLS).;Healthy controls will be age matched, gender matched and BMI matched with the total KOA group (i.e. similar mean ± standard deviation as total KOA group, except for gender which will be about the same ratio as the total KOA group (+- 3%)).

Exclusion criteria

Potential KOA subject meeting any of the following criteria will be excluded from participation in the study:
- Diagnosed with hip osteoarthritis, rheumatoid arthritis or any other form of inflammatory arthritis (i.e., septic arthritis, crystal arthropathy)
- Has a lower extremity joint replacement.
- Has had a knee related injury last year.
- Not signed an informed consent.;A potential control subject meeting any of the following criteria will be excluded from participation in the study:
- Diagnosed with a musculoskeletal disease.
- Has a lower extremity joint replacement.
- Has had a knee related injury last five years.
- Has knee-related problems.
- Not signed an informed consent.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2018

Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	14-09-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2018
Application type:	Amendment
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	NL61592.029.17