Real-life and challenging gait skills to evaluate performance after cruciate-retaining total knee arthroplasy

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1) To compare gait quality in daily life and challenging gait skills of patients 1 year following cruciate-retaining TKA compared to a healthy, age and gender matched cohort.2) To compare pre- to post-operative cruciate TKA status in quantity and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON49702

Source
ToetsingOnline

Brief title
Challenge CR

Condition

- Bone and joint therapeutic procedures

Synonym
degenerative joint disease, Knee osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Smith & Nephew

Intervention

Keyword: cruciate retaining, gait, stability, total knee arthroplasty, wearable sensors

Outcome measures

Primary outcome

Difference between TKA-CR subjects 1 year post-operatively and healthy controls on average gait speed from gait bouts identified during 5-7 days continuous monitoring in real life (free-living).

Secondary outcome

Continous monitoring:

- Quantity of gait bouts/hour
- Peak turning velocity
- Mean stride length
- Mean stride time
- Coefficient of variation of stride time
- Asymmetry of step time
- Coronal trunk range of motion
- Foot strike angle

Challenging gait tasks:

Peturbations:

- Foot placement post-perturbation
- CoM trajectory during the perturbation and subsequent steps
- Margin of stability
- CoP trajectory

- Spatiotemporal gait parameters (step width, step length)

Up/downhill walking:

- Sagittal knee moments

- Knee adduction moments

- Knee joint angles

- Ankle joint moments and angles

- Hip joint moments and angles

- Toe-out angle

- Toe-off angle

- Spatiotemporal gait parameters

Study description

Background summary

The main goal of a total knee arthroplasty (TKA) with cruciate retaining (CR) is to reduce pain and improve mobility during daily life. However, the effectiveness of this procedure, in terms of improving quality of gait, is still under debate. In addition, the objective assessment of gait function has mostly been limited to simple, lab-based tasks. The current study therefore aims to investigate whether gait function, assessed in real-life conditions as well as during challenging lab-based tasks, fully recovers 1 year post surgery. It is expected that, although patients will improve from pre- to post surgery, their gait will still be impaired in comparison to healthy controls.

Study objective

1) To compare gait quality in daily life and challenging gait skills of patients 1 year following cruciate-retaining TKA compared to a healthy, age and gender matched cohort.
2) To compare pre- to post-operative cruciate TKA status in quantity and quality of gait and turning in daily life (continuous monitoring) and

challenging gait skills.

Study design

Case-control study, with baseline assessment and prospective follow-up at 1 and 2 years post-operatively.

Study burden and risks

The burden of participation to this study is limited to gait assessments pre-operatively, 1 and 2 year postoperatively at the Sint Maartenskliniek (2-3 hrs each assessment), and around these time points wearing inertial measurement units embedded in a sock and on the belt for 5 days. Additionally, 2/3 questionnaires will be filled out at these time points (total duration incl. lab maesurements is 2.5 hours). Radiographic analyses will be performed once to determine the placement and migration of the knee prosthesis (20 minutes). Risks are minimal as the subjects will wear a harness attached to the ceiling to prevent falls during the gait assessment in the clinic. Also, radiation exposure is minimal during the radiographic measurements. The risks related to the surgery are minimal, and most importantly, are not higher than the conventional knee prosthesis placed in our hospital. The measurements at baseline, 3 and 24 months comprise an addditional burden for the participants as they are not part of the regular care. Therefore, additional travel expenses that are related to those measurements will be refunded.

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

Patients undergoing total knee arthroplasty:
40-80 years old
Non-inflammatory knee osteoarthritis as indicated by radiology
Set to receive a primary total knee arthroplasty
In stable health

Healthy controls:
40-80 years old
In stable health

Exclusion criteria

Patients undergoing total knee arthroplasty:
BMI > 35
Surgery to the study knee
Active infection, systemic infection
Trauma to study knee
Previous knee, hip, or ankle replacement surgery or planned to have one in the next 24 months
Any musculoskeletal or neurological disease other than osteoarhritis that impairs gait or balance
Severe damage to any knee ligament other than anterior cruciate ligament

Healthy controls:
Moderate to severe pain in one or both knees, hip or ankle (>4 on items 3-6 form Brief Pain Inventory)
Previous replacement surgery to knee, hip or ankle or planned for future replacement surgery

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:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-08-2020
Enrollment:	64
Type:	Actual

Medical products/devices used

Generic name:	total knee prosthesis with posterior cruciate retaining
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-06-2020
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

ID: 27446
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL71606.091.19