

Recovery of walking after Knee Replacement with ROCC

Published: 20-05-2008

Last updated: 10-05-2024

The objectives of this study are answering these two questions: 1. Do patients with KR-R show a clear and fast recovery of walking? 2. Are there any other parameters that improve clearly and quickly after KR-R?

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON31531

Source

ToetsingOnline

Brief title

Recovery of walking after TK-R

Condition

- Joint disorders

Synonym

knee arthrosis, knee osteoarthritis

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Biomet Nederland, de overheid van de Islamitische Republiek Iran (beurs voor de promovendus en deel van het exploitatie-budget); plus een aanvulling van de industrie

Intervention

Keyword: functional recovery, gait analysis, knee replacement, ROCC

Outcome measures

Primary outcome

Gait parameters and directly related measurements:

- maximum walking velocity
- comfortable walking velocity
- gait kinematics
- the DynaPort KneeTest for activities of daily living (ADL).

Secondary outcome

[Independent: Demographic data, such as age, gender, weight, medical intake (co-morbidity, co-interventions).]

Knee Society Knee Score

Scores on

questionnaires:

- the SF36 for health-related quality of life.
- the WOMAC for osteoarthritis-related quality of life
- the TAMPA scale for fear of movement
- the IPAQ for the amount of physical activity
- a question about the priority given to daily routines
- VAS-scores before and after the experiment, as to expected / experienced

pain, fatigue, anxiety

Quadriceps strength

Oxygen consumption during walking

Serum concentrations of inflammation mediators, such as IL6 and CRP.

Study description

Background summary

Currently, 300,000 Dutch residents suffer from knee OA, with a total of 7,500 Total Knee Replacement (TKR) performed yearly (Lenssen et al., 2006). In view of the ageing of the population, these numbers are expected to increase. TKR is often regarded as a successful procedure to relieve pain and restore function. Still, functional recovery after Knee Replacement (KR) is slow, and some patients continue to have problems, e.g., slow walking. In our group, we have much experience with the study of walking recovery after TKR. Informal experience suggests that walking recovery after TKR with the ROCC (KR-R) is unusually fast.

Study objective

The objectives of this study are answering these two questions:

1. Do patients with KR-R show a clear and fast recovery of walking?
2. Are there any other parameters that improve clearly and quickly after KR-R?

Study design

A prospective cohort study. A group of not more than 20 patients with unilateral osteoarthritis of the knee (the "patients") will be followed from shortly before to 6 weeks, 6 months, and, if possible, 12 months after Knee Replacement with the ROCC (KR-R). We will measure oxygen cost of walking, gait kinematics, quadriceps strength, and movement acceleration during daily activities, concentrations of inflammation mediators, and patients' self-reports: VAS- scales for pain, TAMPA for kinesiophobia, SF-36 for health-related quality of life, WOMAC for osteoarthritis-related quality of life, and the IPAQ for physical activity.

Study burden and risks

In the present protocol, measurements will not take longer than 3 hours per measurement session per participant. Technically, the risks are very low. Two researchers (one of whom with at least a paramedical education) will be present during all measurement sessions, and during treadmill sessions participants are secured to a harness so that falling is impossible. Patients are invited to bring another person, we take a lot of time for personal contact, and patients are usually very positive about their experience with us.

Contacts

Public

Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV Amsterdam
Nederland

Scientific

Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

age between 40 and 80, unilateral osteoarthritis of the knee, waitlisted for knee replacement with the ROCC at the Gemini Hospital in Den Helder or the Albert Schweizer Hospital in Zwijndrecht

Exclusion criteria

replacement of the other knee (earlier, scheduled, or to be scheduled), revision operation, any conditions than osteoarthritis of the knee that interfere with gait (such as neurological, skeletomuscular, or obstetric disorders), any conditions that render the patient unfit to be tested (such as pulmonary and/or cardiac disorders), any conditions that render the patient unable to understand or adhere to the protocol (such as cognitive, visual and/or language problems, or hand problems, that render the patient unfit to fill-in the questionnaires)

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-11-2007

Enrollment: 20

Type: Anticipated

Ethics review

Approved WMO

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	NL20287.029.07