Preoperative prediction of postoperative physical function, at 6 weeks, in patients with total knee arthroplasty based on physical fitness and patient characteristics; a prospective cohort study

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Primary Objective: To investigate if a risk model can be made, based on physical fitness and patient characteristics, to predict the recovery of physical function 6 weeks after total knee arthroplasty.Secondary Objective(s): To explore if this model...

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

Summary

ID

NL-OMON54116

Source
ToetsingOnline

Brief title
Preoperative prediction of postoperative physical function in TKA patients.

Condition

- Other condition
- Bone and joint therapeutic procedures

Synonym
Knee Osteoarthritis

Health condition

gewrichts-aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Functional recovery, Prediction, Preoperative, Total Knee arthroplasty

Outcome measures

Primary outcome

The primary outcome is postoperative physical function (KOOS) 6 weeks after TKA surgery. Predicted by physical fitness and patient characteristics measured during the preoperative assessment. The KOOS is a measurement tool to assess physical recovery of knee function. It evaluates both short and long-term outcomes and consists out of 42 items dived in 5 subscales;

- Pain

- Symptoms

- ADL

- Sport-recreation

- Quality of life (QoL)

Determinants:

Numeric rating score (NRS)

Pain

score 0-10

A higher score indicates more pain.

30sec Timed Chair Stand Test (30secTCST)

Lower extremity strength

More repetitions indicate a better strength. Counts the repetitions of making the transfer from sit to stand during 30 seconds.

2 minute walking test (2MWT)

Walking ability

A longer distance (meters) indicates a better walking ability. Self-paced walking ability and functional capacity test.

Timed up and go test (TUG)

Walking ability and balance

A shorter time indicates a better walking ability and balance during de transfer from sit to stand and walking 3 meters.

Hand grip strength (HGS)

Strength

Strength in kilogrammes. Measures maximal hand grip strength with the JAMAR dynamometer.

De Morton Mobility Index (DEMMI)

Activities

The higher the score, the better the activities. Measures performing activity tasks independently.

Besides the primary outcome and determinants several other relevant study parameters will be collected which describe the characteristics of the participants, like age, sex, body mass index (in kg/m2). Comorbidity will be recorded using the American Society of Anesthesiologists (ASA) classification (I-IV, a higher score indicates less fit for surgery).

Secondary outcome

N.A.

Study description

Background summary

One of the most common degenerative joint disorders is osteoarthritis (OA). It is most frequently localized in the knee joint. In 2019, the prevalence of knee osteoarthritis (KOA) in the Netherlands reached 704.600 patients. The incidence number will increase with age and is higher in women (29.800) than in men (18.900) (1). There are several risk factors for the development of KOA, these can be divided in endogenous (Age; Sex; Heredity; Ethnic origin; Postmenopausal changes) and exogenous factors (Trauma; Overweight; Restrictive joint surgery; Lifestyle factors) (2).

Progressive loss of joint cartilage, osteophyte formation and sclerosis of the subchondral bone leads to reduced mobility, strength, instability and pain (3). This results in limitations in activities of daily life (ADL), work and leisure (3, 4). The treatments of KOA always starts with a conservative approach. If the conservative approach does not produce sufficient results, joint replacement surgery can be considered (5). Total knee arthroplasty or replacement (TKA/TKR) is regarded as the gold standard for the treatment of KOA

(6). In 2019 TKR was performed 25.881 times in the Netherlands. In 2020 there was seen a drop in surgeries due to COVID-19. Nevertheless, 19.501 TKR*s were performed (7). Predictions with incidence numbers from 1997-2005 predict 57.893 TKR*s in 2030, that is an increase of 297% (8).

Due to the increase in patients with KOA, healthcare costs are rising. Of all these costs, 54% are spent in hospital care (3). The hospital care is constantly evaluating in order to cope with the influx of patients and in order to be able to continue and deliver the most optimized care. Therefore enhanced recovery pathways such as enhanced recovery after surgery (ERAS), fast track, and rapid recovery were developed (9). The idea behind these different multidisciplinary pathways is a reduction of postoperative physical and psychological stress and thereby a reduction in length of stay (LOS) and healthcare costs (9). The first positive results of an enhanced recovery pathway was found in high-risk elderly patients who underwent colonic surgery (10). Enhanced recovery in elective orthopedic arthroplasties showed a decreased LOS from 5-11 days to <= 4 days (11).

A study in total hip replacements has shown that physical fitness before surgery is a major predictor of postoperative inpatient recovery (12). A cluster of physical measurements was used to distinguish between patients with high and low risk on postoperative inpatient delayed recovery. Delayed inpatient recovery manifests itself in a longer hospital stay and can be accompanied by postoperative complications (12). Also patient characteristics turn out to be important. The study of Hoogeboom et al. (13) showed that patient-related characteristics can explain delayed inpatient functional recovery after TKA. Literature shows that physical therapy has significant positive effects on the level of physical activity within the first 3 months after TKA (14).

Until now no risk inventory prediction model have been made for the prediction of physical function at six weeks after TKA. Therefore we want to develop a risk inventory prediction model. This model has an added value for clinical practice because if we*re able to develop a well-performing prediction model, the perioperative process of TKA patients can be improved.

Study objective

Primary Objective: To investigate if a risk model can be made, based on physical fitness and patient characteristics, to predict the recovery of physical function 6 weeks after total knee arthroplasty.

Secondary Objective(s): To explore if this model is able to distinguish between low risk and high risk of a delayed recovery of physical function.

Study design

This prospective cohort study will collect data by performing preoperative assessment of physical fitness before surgery, by all included patients. The preoperative assessment will take place at MUMC+, Zuyderland Medical Centre and the Annadal clinic. 6 weeks after surgery the Knee Injury and Osteoarthritis Outcome Score (KOOS) will be conducted by phone.

Study burden and risks

During this examination, the burden on the patient is minimal. The patient will visit the physical therapist once for the preoperative assessment. This appointment will follow already scheduled appointments with the specialist and will last up to 45 minutes. In addition, the subject will receive a one-time phone call. This phone call will be a maximum of 10 minutes, for completing the KOOS questionnaire. The preoperative assessment does not involve any risks.

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 will be included if:
- They are scheduled for a primary TKA
- They are able to perform the preoperative assessment
- They are able to fulfill the KOOS by phone 6 weeks postoperatively

Exclusion criteria

Patients will be excluded if:
- They get a hemi-knee or revision surgery
- They get a primary TKA not due to osteoarthritis of the knee
- They weren't able to perform the preoperative assessment
- They weren't able to fulfill the KOOS by phone 6 weeks postoperatively

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-10-2022
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO

Date:	22-07-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-02-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL78977.068.21