Observational cohort study to assess the association between mitochondrial function and recovery after a primary total knee arthroplasty in the elderly.

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

Summary

ID

NL-OMON47672

Source
ToetsingOnline

Brief title
Mitochondrial function and recovery

Condition

- Joint disorders

Synonym
joint wear, Muscle weakness

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research

Source(s) of monetary or material Support: Clinical Research Organisation

Intervention

Keyword: Arthroplasty, Mitochondrial (dys)function, Osteoarthritis, Sarcopenia

Outcome measures

Primary outcome

- Total score on the KOOS questionnaire

Secondary outcome

- Time in seconds to complete the TUG test

- Daily activity (in steps per day), measured continuous with Withings

smartwatch

- Skeletal muscle mass (in kg/m2), measured weekly by Withings Body smart scale

- Quadriceps strength (in kg), measured by the CITEC hand-held dynamometer

- Maximal grip strength (in kg), measured by the Jamar dynamometer

- Maximal grip strength (in kg), measured at home by the Theripear

Study description

Background summary

Sarcopenia is an age-related decline in muscle mass and thought to be accelerated by mitochondrial dysfunction. In a study in patients receiving surgery for a hip fracture, 40% of patients were identified as sarcopenic and in muscle tissue taken during surgery sarcopenia was correlated to a lower mitochondrial function. Sarcopenia is equally prevalent in patients who receive a total knee arthroplasty (TKA) for osteoarthritis . It is known that sarcopenia has a detrimental effect on functional recovery after surgery and due to the relationship between sarcopenia and mitochondrial dysfunction, there might be a rationale to identify and treat mitochondrial dysfunction in patients planned for a TKA. However, the effect of mitochondrial function on the recovery after a TKA is not known and thus it cannot be stated that

treating mitochondrial dysfunction will be beneficial for the recovery.

Study objective

The objective of this study is to determine the association between mitochondrial function (activity and protein abundance of electron transport chain complexes I, II, III, IV and V) before TKA and change in KOOS score before versus 6 + 12 months after TKA.

Study design

This is an observational cohort study to assess the relationship between mitochondrial function and recovery after a primary total knee arthroplasty in the elderly.

Study burden and risks

The benefits of this study are to potentially gain a pre-operative prognostic marker for the recovery after a TKA and real-time information on the recovery by use of activity, bioimpedance and grip strength measurements at home, which offers the surgeon a chance to intervene with intensified physical therapy if necessary. The burden for the patient consists of using the at home devices for 6 months after the TKA. The additional muscle sample taken during the surgery is not expected to yield any adverse effect on the recovery process. The questionnaires and other objective and functional outcome measures will be performed during the planned outpatient clinic visits.

Contacts

Public
Centre for Human Drug Research

Zernikedreef 8
Leiden 2333CL
NL
Scientific
Centre for Human Drug Research

Zernikedreef 8
Leiden 2333CL
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Male or female of 60 years of age or older.
2. Indication for an unilateral, primary total knee arthroplasty, due to moderate to severe osteoarthritis of the knee joint (grade 3 * 4 on the Kellgren and Lawrence scale).
3. Formerly able to walk independently.
4. Signed informed consent prior to any study-mandated procedure.
5. Willingness to perform the at home measurements (Withings Body and Theripear).
6. Able to use a smart phone (iPhone or similar).

Exclusion criteria

1. History of a performed arthroplasty of the lower extremities within 12 months before study enrollment and having planned any arthroplasty of the lower extremities within 12 months after study enrollment.
2. History (within 3 months before screening) of alcohol consumption exceeding 2 standard drinks per day on average (1 standard drink = 10 grams of alcohol).
3. Concomitant disease or condition that could interfere with, or for which the treatment of might interfere with, the conduct of the study, or that would, in the opinion of the Investigator, pose an unacceptable risk to the subject in this study.
4. Underlying chronic disease, which, in the opinion of the investigator would interfere with study participation or the validity of the measurements.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	19-02-2018
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	02-11-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-05-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	NL61972.056.17

Study results

Date completed: 16-05-2019

Results posted: 09-06-2020

First publication
01-01-1900