Submaximal cardiopulmonary exercise testing in patients with knee osteoarthritis scheduled for total knee arthroplasty: a feasibility study.

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

Summary

ID

NL-OMON50982

Source
ToetsingOnline

Brief title
Feasibility of CPET in patients prior to TKA.

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
gonarthrosis, knee osteoarthritis

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: Cardiopulmonary Exercise Testing, Feasibility, Knee, Osteoarthritis

Outcome measures

Primary outcome

Feasibility of CPET will be assessed against five criteria: 1) recruitment rate

*20%; 2) CPET performance rate *90%; 3) *90% of participants reached the VAT;

4) no serious adverse events; and 5) *80% of participants had a positive

attitude towards CPET.

Secondary outcome

Aerobic capacity is determined by the VO2 at the VAT and the oxygen uptake

efficiency slope (OUES).

Study description

Background summary

Higher aerobic capacity before surgery, as indicated during submaximal exercise testing by the oxygen uptake (VO2) at the ventilatory anaerobic threshold (VAT), is assumed to be prognostic for a better and faster postoperative recovery in patients with knee osteoarthritis (OA) undergoing total knee arthroplasty (TKA). Cardiopulmonary exercise testing (CPET) is the gold standard to measure aerobic capacity; however, it is unclear whether it is feasible to perform CPET using cycle ergometry in patients with knee OA prior to TKA surgery. The hypothesis is that performing CPET is feasible and participants will meet the feasibility criteria for success.

Study objective

The primary objective of this study is to investigate the feasibility of CPET

in patients with knee OA three to six weeks prior to TKA surgery in three domains: a) recruitment rate of participants who are representative of the target study population; b) reaching the VAT during CPET; and c) acceptability and suitability. The secondary objective is to investigate aerobic capacity of the study population and to compare values with normative values.

Study design

Cross-sectional feasibility study.

Study burden and risks

CPET is considered a safe procedure. Participants perform the CPET instead of a walking test following the standard preoperative screening and complete a questionnaire to examine their experiences. The investigator will contact the participants one week after the CPET to inquire whether they have developed any complaints afterwards. Benefit from participation is that patients objectively get insight in their preoperative aerobic capacity.

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

* The patient is scheduled for primary unilateral TKA surgery in MUMC+ or St. Anna Hospital;
* Diagnosis of OA;
* CPET can be performed three to six weeks before TKA surgery following the preoperative screening;
* Mastery of the Dutch language.

Exclusion criteria

* Undergoing revision arthroplasty, bilateral TKA or hemi-arthroplasty surgery;
* Contraindications for CPET according to the American Thoracic Society (ATS) Statement on CPET and following the American Heart Association/American College of Sports Medicine (AHA/ACSM) Health/Fitness facility preparticipation screening questionnaire;
* Unable to get on and off a stationary bike;
* Complete dependence on a wheelchair;
* Serious comorbidities (e.g. malignancy, stroke);
* Cognitive impairments;
* Unable to sign informed consent.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-05-2021
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	18-03-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-04-2021
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
ClinicalTrials.gov	NCTID04773262
CCMO	NL76561.068.21