PAPRIKA study

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Ethical review	Not available
Status	Pending
Health condition type	Renal and urinary tract therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON57534

Source
Onderzoeksportaal

Brief title
The association between patient-reported preoperative fitness and postoperative outcomes.

Condition

- Renal and urinary tract therapeutic procedures
- Endocrine gland therapeutic procedures
- Vascular therapeutic procedures

Synonym
We aim to include all surgical procedures that require anesthetic support, excluding acute surgical treatments and outpatient surgeries.

Research involving
Human, Data

Sponsors and support

Primary sponsor: Máxima MC
Source(s) of monetary or material Support: Máxima MC

Intervention

- Other intervention

Explanation

N.a.

Outcome measures

Primary outcome

Primary Outcome Measures Complications: Occurrence of postoperative complications within 30 days after surgery.
Mortality: Postoperative death within 30 days after surgery.
Survival: Death within 1 year after surgery.

Secondary outcome

Secondary Outcome Measures Length of hospital stay: Total duration of hospitalization, measured in days.
Readmissions: Number of hospital readmissions within 30 days after discharge.
Morbidity: Assessment of health status after surgery up to one year post-procedure.

Study description

Background summary

Cardiorespiratory fitness (CRF) is defined as the capacity to absorb, transport, and utilize oxygen for cellular respiration, reflecting an individual's functional capability. Surgical procedures requiring anesthetic support impose increased metabolic demands on the body's cardiorespiratory system. Patients with low CRF have a higher risk of postoperative complications, including mortality and prolonged hospital stays. Particularly in patients with low CRF, promising effects have been observed from prehabilitation programs aimed at improving CRF before surgery. This underscores the importance of timely identification of patients with low CRF to advise, support, and consider prehabilitation.

In the current clinical preoperative setting, CRF is subjectively estimated by anesthesiologists using the PREOP checklist. If low CRF is suspected with an associated increased risk of

complications, further assessment is conducted before surgery. Evaluating CRF through an objective measurement of oxygen uptake (VO2 peak) during a maximal cardiopulmonary exercise test (CPET) is considered the gold standard, leading to a more accurate risk assessment. Additionally, CPET provides valuable insights into the causes of exercise limitations. Various risk thresholds for objectively measured preoperative VO2 peak have been described to predict postoperative complications. However, CPET is expensive, labor-intensive, and requires extensive (patho-)physiological knowledge for interpretation, especially in patients with multiple comorbidities, making it less broadly applicable for preoperative risk assessment.

Patient-reported questionnaires are often used as an alternative for estimating VO2 peak. The FitMáx questionnaire, developed and validated by the Sports Medicine Department of Máxima MC, is designed to accurately assess CRF. The correlation between VO2 peak estimated with FitMáx and objectively measured VO2 peak during CPET is r=0.94 (0.92-0.95) in both patients and healthy individuals [1].

In a recent publication [2], we compared different patient-reported questionnaires (FitMáx, Veterans-Specific Activity Questionnaire (VSAQ), Duke Activity Status Index (DASI), and the PREOP checklist) for estimating preoperative CRF in non-surgical patients. We applied literature-based, population-dependent cutoff values for peak oxygen uptake and demonstrated that FitMáx performed better in identifying high-risk patients scoring below the defined cutoff values compared to DASI and PREOP, and at least as well as VSAQ. A key critique from reviewers of this study was that it involved non-surgical patients who underwent CPET for other reasons and completed the questionnaires. Additionally, they raised the question of whether the questionnaire results, beyond VO2 peak threshold values, could also be used to assess the risk of complications.

Now, we aim to evaluate the accuracy of preoperative CRF assessment in relation to surgical outcomes (e.g., complications, hospital stay duration, and mortality). We will administer the FitMáx (alongside VSAQ, DASI, and PREOP) to patients undergoing surgical procedures requiring anesthetic support at Máxima MC. We will use a modified FitMáx, which, in addition to assessing walking, stair climbing, and cycling, includes daily activities. This modification was necessitated by the increasing use of electric bicycles, prompting an essential update in our ongoing validation study at the hospital.

Study objective

In this study, we investigate the possibility of preoperatively estimating the risk of complications in patients using the FitMáx, VSAQ, and PREOP checklist. These questionnaires are automatically administered via the Mijn MMC patient portal two weeks before the scheduled surgery date. Relevant data regarding the surgery, postoperative outcomes, and survival are tracked for up to one year after the procedure.

After data collection, we evaluate the association between patient-reported VO2 peak through the questionnaires and postoperative outcomes (e.g., complications, morbidity, mortality, length of hospital stay). Additionally, we compare the associations and practical usability of the FitMáx with those of the VSAQ, DASI, and PREOP checklist.

Study design

This study consists of two phases.

In the first phase, the FitMáx, VSAQ, and DASI will be combined into a single questionnaire for patients undergoing surgical treatment at Máxima MC. This questionnaire will be provided two weeks before the planned surgery via Mijn MMC, along with the standard PREOP checklist. Through Mijn MMC, we will request consent to access surgical reports, associated postoperative follow-up correspondence, relevant patient characteristics, length of hospital stay, and documented complications. Completing the questionnaire will take approximately five minutes.

In the second phase, we will collect data on complications and mortality from the electronic patient record (EPR) for up to one year after surgery. We will assess the accuracy of these questionnaires in preoperatively estimating the risk of postoperative complications and overall surgical outcomes in patients.

Study Participants
Inclusion will be automatically facilitated via Mijn MMC, where patients, after providing consent, will receive access to the questionnaires.

Inclusion Criteria

- Patients scheduled for surgical treatment at Máxima MC
- ≥18 years old

Patients will be asked via Mijn MMC whether they are willing to participate in the questionnaire study. Once they agree, the questionnaires will become visible.

Intervention

FitMáx©
DASI
VSAQ
PREOP

Study burden and risks

Neglectible

Contacts

Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion

1. Patients scheduled for a surgical procedure at Máxima MC;
2. ≥18 years old.

Exclusion criteria

Acute surgical intervention (<7 days) and outpatient surgical interventions

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2025
Enrollment:	10000
Duration:	12 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Not available

Date:	15-05-2025
Application type:	First submission
Review commission:	Validatie nWMO registratie door CCMO

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
Research portal	NL-010038