Development of a clinical assessment tool to estimate cardiorespiratory fitness (preoperatively)

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23304

Source NTR

Brief title Validation of the FitMáx© questionnaire

Health condition

- Cardiac patients
- Lung patients
- Oncological patients

Also healthy subjects were included in this study

Sponsors and support

Primary sponsor: none **Source(s) of monetary or material Support:** This work was partially funded by the Stichting SOS and by the National Foundation Against Cancer.

Intervention

Outcome measures

Primary outcome

Is the FitMáx@ questionnaire a valid instrument to measure cardiorespiratory fitness expressed as VO2-max?

Secondary outcome

- Is the FitMáx© questionnaire a more valid instrument to measure cardiorespiratory fitness compared to existing/validated international questionnaires?

- Is the FitMáx© questionnaire without the maximum cycling capacity, still a valid instrument to measure physical fitness? (cultural adaptation for international use)

- Is the FitMáx© able to estimate preoperative risk for complications during or after surgery?

Study description

Background summary

The aim of this trial is to develop and validate a questionnaire as a clinical assessment tool for cardiorespiratory fitness (CRF) in several patient groups. The questionnaire we developed consists of three questions about the maximum capacity for walking/running, cycling and stairclimbing. These are recognisable activities for the general Dutch population.

All patients and healthy subjects who are scheduled for a cardiopumonary exercise test (CPET) in the Máxima Medical center are approached for participation in this trial. After receiving signed informed consent and completed questionnaire, the data from the CPET are retrospectively obtained from the electronic patients files.

The results of the questionnaire will be compared with the resultst of the cardiopulmonary exercise test in the same patients. Based on the scores of the questionnaire together with simple demographic characteristics a model will be developed to calculate the maximum oxygen uptake (expressed as VO2peak). Moreover we will conduct analyses to determine whether the FitMáx[©] is able to estimate preoperative risk for complications during or after surgery. Therefore we will determine cut-off points for VO2peak.

In the same research population existing and validated physical activity questionnaires are used to compare resultst of the FitMáx© questionnaire with. These questionnaires are; the veterans specific activity questionnaire (VSAQ), the duke activity status index (DASI), the physical fitness questions of the EORTC-QLQ C30 and a Metabolic Equivalent of a Task (MET) questionnaire used for preoperative screening in the Netherlands (validation of the preoperative questionnaire was not found in literature).

Study objective

It is hypothesized that the FitMáx $\[mathbb{C}\]$ questionnaire is a valid clinical assessment tool for CRF compared to the gold standard, a cardiopulmonary exercise test. Moreover we believe the FitMáx $\[mathbb{C}\]$ to be fairly accurate in the preoperative risk assessment prior to surgery.

Study design

The scores of the FitMáx©, VASQ, DASI, EORTC-QLQ C30 and preoperative MET questionnaire are collected within 42 days from the cardiopulmonary exercise test.

Intervention

No interventions are used in this study. Patient data which is used is collected in the context of standard clinical care.

Contacts

Public

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Eligibility criteria

Inclusion criteria

- Patients and healthy subjects who perform a cardiopulmonary exercise test in Máxima Medical Center

- Signed informed consent is received

Exclusion criteria

- Patients younger than 18 years
- Submaximal exercise test due to early abortion of the test

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Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Suspended
Start date (anticipated):	01-05-2018
Enrollment:	800
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description

More information on the data gathered, the analysis used, and calculations used in the model is available upon reasonable request. The use of FitMáx is free when used from the website or when incorporated in studies that help us to further validate the questionnaire in different settings and populations. In addition, there is a commercial licensed model available for usage of the questionnaire in different settings. More information can be found on https://fitmaxquestionnaire.com/.

Ethics review

Positive opinion
Date:
Application type:

28-04-2020 First submission

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
NTR-new	NL8559
Other	METC Máxima MC; nWMO : N18.051

Study results

Summary results https://doi.org/10.2147/IJGM.S355589