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

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Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23304

Bron
NTR

Verkorte titel
Validation of the FitMáx© questionnaire

Aandoening

- Cardiac patients
- Lung patients
- Oncological patients

Also healthy subjects were included in this study

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: This work was partially funded by the Stichting SOS and by the National Foundation Against Cancer.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

It is hypothesized that the FitMáx© questionnaire is a valid clinical assessment tool for CRF compared to the gold standard, a cardiopulmonary exercise test. Moreover we believe the FitMáx© to be fairly accurate in the preoperative risk assessment prior to surgery.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Máxima MC
Renske Meijer

040 888 8000

Wetenschappelijk

Máxima MC
Renske Meijer

040 888 8000

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients and healthy subjects who perform a cardiopulmonary exercise test in Máxima Medical Center
- Signed informed consent is received

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients younger than 18 years

- Submaximal exercise test due to early abortion of the test
- Incomplete questionnaire

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-05-2018
Aantal proefpersonen:	800
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
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/.

Ethische beoordeling

Positief advies

Datum:	28-04-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8559
Ander register	METC Máxima MC; nWMO : N18.051

Resultaten

Samenvatting resultaten
https://doi.org/10.2147/IJGM.S355589