Reproducibility, responsiveness and construct validity of a 6-minute walk-run test in patients with a heart disease.

Gepubliceerd: 13-10-2009 Laatst bijgewerkt: 18-08-2022

The 6minute walk run test is reproducible, valid and has a higher responsiveness as the 6 minute walk test in patients with a heart disease.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22935

Bron
NTR

Verkorte titel
The 6-minute walk- run test in patients with a heart disease.

Aandoening

6 minute walk test
6 minute walk run test
patients with a heart disease

Ondersteuning

Primaire sponsor: Maastricht University Medical Center
Overige ondersteuning: Maastricht University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

6 minute walk-run test.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Patients with a heart disease can participate in a rehabilitation program in the MUMC+. Before rehabilitation starts a 6- minutes walk test which assesses the exercise tolerance level is performed to have baseline measurements. These are used to evaluate the progress and to divide patients into rehabilitation groups. The problem is that this test is not that responsive in (less severe) patients. Therefore a new test is designed, called the 6-minutes walk-run test. In this test, with the same duration as the 6- minutes walk test, also running is allowed.

Objective of the study:

The objective in this study is threefold. First, to test the test-retest reproducibility of the 6-minutes walk-run test. Secondly, to test the responsiveness and to compare this with the 6–minutes walk test. Further, to test the construct validity of the 6-minutes walk-run test in a convergent way with the VO2max and in a divergent way with the Functional Reach and compare this with the results of the 6-minutes walk test.

Study design:

The study is divided into two parts. In the first part the test-retest reproducibility and the responsiveness is investigated in a group of patients with a coronary heart disease. In the second part, the test-retest reproducibility, the responsiveness and the construct validity is tested in a population of heart failure patients. Both study parts have a prospective cohort design, with a cross sectional part to investigate the test-retest reproducibility.

Study population:

In the first part the population is patients with coronary heart disease (myocardial infarction, heart bypass surgery, or/and valve reconstruction surgery). In the second part the population

is patients with heart failure (a syndrome in which the circulation function of the heart is insufficient for the normal demand of oxygen and nutrients).

Primary study parameters/outcome of the study:

The main study parameter is the 6-minutes walk-run test.

Secundary study parameters/outcome of the study:

Other study parameters are the 6-minute walk test, the Functional reach test and the VO2max test.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

During normal rehabilitation, the patients have several tests and activities which equal the exertion in this tests. Secondly, there is no use of invasive interventions. Thirdly, the patients are checked if they are in shape to fulfill the rehabilitation program. Therefore, the risks faced by the patients are no greater than the risks they face during normal rehabilitation. Furthermore, the study participants have the same rehabilitation program as normal.
The additional burden placed on the patients, will be the extra time with the investigator before the rehabilitation. The tests will be on the same day and before the rehabilitation, with this the burden will be as minimal as possible.

Doel van het onderzoek

The 6minute walk run test is reproducible, valid and has a higher responsiveness as the 6 minute walk test in patients with a heart disease.

Onderzoeksopzet

6 minute walk-run test:
Start of rehabilitation (twice), end of rehabilitation.

6 minute walk test, VO2max, Functional reach:
Start of rehabilitation, end of rehabilitation.

Onderzoeksproduct en/of interventie

None.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with a myocardial infarction, heart surgery (bypass and valve reconstruction) or heart failure;

2. Patients who can and are willing to particicpate in a rehabilitation program;

3. Patients who are minimal 18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with only other heart diseases (rhytmproblems);

2. Patients with walking disorders;

3. Patients without a need for rehabilitation;

4. Bloodpressure > 180/100 mmHg;

5. Resting heartrate > 120 bpm.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2009
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-10-2009
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	NL1971
NTR-old	NTR2088
Ander register	ABR number : 29285
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A