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

No registrations found.

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

Summary

ID

NL-OMON22935

Source
NTR

Brief title
The 6-minute walk- run test in patients with a heart disease.

Health condition

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

Sponsors and support

Primary sponsor: Maastricht University Medical Center
Source(s) of monetary or material Support: Maastricht University Medical Center

Intervention

Outcome measures

Primary outcome

6 minute walk-run test.

Secondary outcome

1. 6 minute walk test;

2. VO2max test;

3. Functional reach.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

None.

Contacts

Public
Postbus 5800
Danielle Berghmans
Maastricht 6202 AZ
The Netherlands
+31 (0)43 3877146
Scientific
Postbus 5800
Danielle Berghmans
Maastricht 6202 AZ
The Netherlands
+31 (0)43 3877146

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2009
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-10-2009
Application type:	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	NL1971
NTR-old	NTR2088
Other	ABR number : 29285
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A