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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON33093

Source
ToetsingOnline

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

Condition

- Heart failures

Synonym
heart surgery, heartfailure, myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 6 minute walk run test, 6 minute walk test, heart patients

Outcome measures

Primary outcome

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

Secondary outcome

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

and the VO2max test.

Study description

Background summary

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.

Study objective

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 burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

•Patients who are diagnosed by an medical doctor with a heart disease: heart infarction and/or heart surgery (bypass and/or valve reconstruction) or heart failure
•Patients who are willing and able to participate in a rehabilitation program
•Minimal 18 years

Exclusion criteria

•Patients with other heart diseases (e.g. rhythm problems, pace maker of ICD implantation) not accompanied by hearth infarction or treated with heart surgery
•Patient with walking disorders (neurologic or orthopaedic).
•People without a need for rehabilitation
•Resting blood pressure >180/100 mm/Hg
•Resting heart frequency > 120 bpm

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2009
Enrollment:	70
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	02-11-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-02-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL29285.068.09
Other	nog niet bekend