The validity of performance tests, the 4 meter gait speed and the 5 repetitions sit to stand test, in patients suffering PF in daily clinical practice

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Objective: The aim of this study is to assess the validity of the 4MGS and 5STS to determine the functional exercise performance of PF patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON42289

Source
ToetsingOnline

Brief title
Performance tests in pulmonary fibrosis: PT-PF

Condition

- Respiratory disorders NEC

Synonym
lung fibrosis, Pulmonary fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Clinimetric research, Exercise, Performance test, Pulmonary Fibrosis

Outcome measures

Primary outcome

The main study parameters are:

4MGS - the maximum gait speed in meters per second (m/sec).

5STS - the shortest time (seconds) required to stand five times from sitting in

a chair.

6WMT - the maximum walking distance (meters).

Secondary outcome

• SF-36 (IPF): 8 dimensions of Health-related quality of life.

• MRC: a self administered questionnaire about perceived breathlessness.

• Self efficacy: self reported activity limitation

• Borg dyspnoe and Borg fatigue

• Pulmonary function, baseline pulmonary test results: FVC, FEV1, DLCO

• Oxygen saturation

• Blood pressure (systolic/diastolic).

• Body Mass Index (height / weight*weight).

• Lean Body Mass (subtracting body fat weight from total body weight).

• Grip strength (Jamar dynamometer).

• Feasibility of performance tests (Likert scale), patient experience.

• Utility of performance tests (Likert scale), assessor experience.

Study description

Background summary

Rationale: Patients with Pulmonary Fibrosis (PF) experience limitations in their ability to exercise and to perform daily activities. Health-related outcomes can be determined from a patient*s ability to perform exercises and daily functional activities, for example, by measuring their walking speed or capacity to rise from a chair. The 4 Meter Gait Speed (4MGS) and the 5 repetitions Sit To Stand (5STS) tests are quick to perform, inexpensive and reliable measures of functional performance, even with less space available. The 4MGS and 5STS have been validated in healthy adults and also in diverse patient groups such as patients with Chronic Obstructive Pulmonary Disease (COPD), however for the PF patient population there is a lack of data. We predict that the 4MGS and 5STS tests will provide useful health outcome markers for the well-being of PF patients and may provide clinicians with similar information obtained from the 6 Minute Walking Test (6MWT). Our working hypothesis is that the 4MGS and 5STS tests would correlate strongly to the walking distance achieved in the 6MWT.

Study objective

Objective: The aim of this study is to assess the validity of the 4MGS and 5STS to determine the functional exercise performance of PF patients.

Study design

Study design: This is a cross-sectional clinical trial and to be repeated after 6 months.

Methods: The 4MGS, 5STS and 6MWT tests will all be carried out on a single day for each PF patient. Validity will be determined by measuring the concurrent and longitudinal concurrent validity. Concurrent validity measures the extent to which a new test correlates with a Gold Standard. In this study, this means the correlation between the 6MWT (Gold Standard) and the 4MGS and 5STS respectively, calculated for 80 PF patients. Data will also be collected on health-related quality of life (SF-36), disease severity (pulmonary function), experienced dyspnoea (MRC and Borg) and fatigue (Borg).

Study burden and risks

Patients suffering from PF will be asked to perform three physical exercise performance tests, the 4MGS, 5STS and 6MWT on a single day. All three tests will be repeated after six months, again on a single day, on the patient*s regular visit to their pulmonologist.

Burden and Risk
These tests are functional exercise and performance tests of daily activity.
The 6MWT is currently part of routine clinical management, but not a standard procedure. Reported complications associated with the performance of the 6MWT are unusual. There is a slight risk of falling and the main burden for the participant is potential perceived dyspnoea and fatigue.
All tests will be performed with continuous monitoring of oxygen saturation and heart rate by peripheral oximetry.
All necessary safety procedures in exercise management will be taken into account.

Benefits
The benefit of this study will be for future PF patients. When 4MGS and 5STS appeared to be valid outcome predictors,, future PF patients will benefit by having to perform exercise tests that are less stressful and of a shorter duration.

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 with PF, visiting outpatient respiratory clinic at St Antonius Hospital in Nieuwegein (Expertise Centre Interstitial Lung disease, cIL) for routine medical control

Exclusion criteria

Absolute contraindications
Acute myocardial infarction (3-5 days); Unstable angina; Uncontrolled arrhythmias causing symptoms or haemodynamic compromise; Syncope; Active endocarditis; Acute myocarditis or pericarditis; Symptomatic severe aortic stenosis; Uncontrolled heart failure; Acute pulmonary embolus or pulmonary infarction; Thrombosis of lower extremities; Suspected dissecting aneurysm; Uncontrolled asthma; Pulmonary oedema; Acute respiratory failure; Acute noncardiopulmonary disorder that may affect exercise performance or be aggravated by exercise (i.e. infection, renal failure, thyrotoxicosis); Mental impairment leading to inability to cooperate;A subject that meets any of the following criteria, will be in- or excluded by the judge of the pulmonologist:;Relative contraindications
Room air SpO2 at rest 85% (arterial oxygen saturation measured by pulse oximetry); Left main coronary stenosis or its equivalent; Moderate stenotic valvular heart disease; Severe untreated arterial hypertension at rest (200 mmHg systolic, 120 mmHg diastolic); Tachyarrhythmias or bradyarrhythmias; High-degree atrioventricular block; Hypertrophic cardiomyopathy; Significant pulmonary hypertension; Advanced or complicated pregnancy; Electrolyte abnormalities; Orthopaedic impairment that prevents walking

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-05-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	23-04-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL51679.100.15