Feasibility, reliability and relevance of quadriceps muscle endurance measurements in people with COPD

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

Summary

ID

NL-OMON43277

Source
ToetsingOnline

Brief title
Measuring muscle endurance in COPD

Condition

- Muscle disorders
- Respiratory disorders NEC

Synonym
airway obstruction, COPD

Research involving
Human

Sponsors and support

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

Intervention

Keyword: COPD, endurance, muscle

Outcome measures

Primary outcome

Reliability of the quadriceps isometric, isokinetic and isotonic endurance will be assessed using a two-way random single measures ICC procedure. Munro*s descriptors will be used to describe the degree of reliability: high, ICC = 0.70 to 0.89 and very high, 0.90 to 1.00. The limits of agreement between measures taken on two days will be established using a Bland-Altman plot for all measurements. The proportion of scores within 2 standard deviations of the mean difference between test-retest values will be used to describe agreement. In order to facilitate the clinical interpretation of reliability results, the minimal detectable change (MDC) at 95% confidence level will be calculated. .

Secondary outcome

Bivariate, linear correlations will be evaluated using a Pearson correlation coefficient for quadriceps isometric, isokinetic and isotonic endurance, and SPPB scores. The strength of the relationship will be described using Munro*s descriptive.

Study description

Background summary

Chronic obstructive pulmonary disease (COPD) is a leading cause of death worldwide. It is estimated that 400000 patients suffer from this disease in the Netherlands. Although COPD is primarily a disease of the respiratory system, a common secondary consequence is quadriceps muscle dysfunction, that is, reduced

muscle strength and/or endurance. These have been associated with important clinical outcomes including, but not limited to, reduced quality of life, exercise intolerance, activities of daily life and hospitalization. Despite the relevance and prognostic value of quadriceps muscle function, these measurements have not been implemented as part of the routine evaluation of patients with COPD. If the recently published, 2014 American Thoracic Society and European Respiratory Society statement on Limb Muscle Dysfunction in COPD, recommends using isometric assessments of quadriceps to assess muscle strength, the most feasible, relevant and reliable way of measuring quadriceps muscle endurance remains to be determined. Furthermore, no study has investigated the association between quadriceps muscle endurance and objectively measured daily physical activity. Further research is also warranted on the use of functional assessment of quadriceps muscle function and its potential relationship to daily life activities.

Study objective

The primary objective is to investigate the measurement properties of isometric, isotonic and isokinetic protocol to assess quadriceps muscle endurance in patients with COPD. Our secondary objective is to determine the relationship between quadriceps strength, endurance and functional performance.

Study design

In this prospective study 20 patients with COPD will be recruited. Demographics, standard spirometry, isometric quadriceps muscle strength and assessment of functional performance (short performance physical battery test) will be collected during an initial visit. Isometric, isokinetic and isotonic assessment of quadriceps muscle endurance measured using a computerized dynamometer will be obtained on two subsequent testing sessions separated at least two days. The test-retest reliability, the minimal detectable change, feasibility of administration of these tests and relationship to muscle strength and functional performance of patients with COPD will be determined.

Study burden and risks

The risks on any undesirable side effects of this study are very low. If any, the muscle function tests could be accompanied by some muscle soreness. This feeling will naturally disappear within two days. At the same time, the benefits of the study are high, because results from this study will show which protocol for measuring muscle endurance is most appropriate to use in daily clinical practice.

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

1) at least 40 years old, 2) Diagnosis of moderate to very-severe COPD based on spirometry according the GOLD classification, 3) able to provide written informed consent, 4) able to follow verbal directions for testing.

Exclusion criteria

1) diagnosed with cardiovascular, neurological or neuromuscular conditions that could affect ability to perform the tests (e.g. stroke, knee osteoarthritis); 2) currently participating in a pulmonary rehabilitation program or been involved in pulmonary rehabilitation in the past 6 months; 3) experienced a COPD exacerbation in the past 3 months, 4) receiving a daily dose > 10mg of oral Prednisone within the past 3 months.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-10-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	04-04-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL59926.091.16