(In)voluntary assessed quadriceps muscle endurance in patients with chronic obstructive pulmonary disease: a cross-sectional observation study.

Published: 25-04-2022
Last updated: 06-04-2024

The primary objective is to assess the relation between involuntary and voluntary assessed quadriceps muscle endurance in patients with COPD.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON51402

Source
ToetsingOnline

Brief title
BIONIC

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic obstructive pulmonary disease; chronic lung disease with persistent obstruction of the airways

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Longfonds (NL)

Intervention

Keyword: Chronic Obstructive, Electrical Stimulation, Muscle, Pulmonary Disease, Quadriceps Muscle, Skeletal

Outcome measures

Primary outcome

The primary outcome will be the electrically evoked isometric quadriceps muscle endurance (fatigue resistance) and voluntary isokinetic (work fatigue index5) and isometric quadriceps endurance (time to fatigue).

Secondary outcome

• Involuntary (electrically evoked) assessed muscle force, early and half relaxation times, 20/50 Hz ratio and normalized maximal rate of force rise (MFR) of the quadriceps

• Voluntary assessed isokinetic total work and work fatigue index10

• Fatigue using the CIS-fatigue

Study description

Background summary

Quadriceps muscle endurance is reduced in patients with COPD. However, no consensus has been reached yet on the best method to evaluate quadriceps muscle endurance. One important aspect is the large variety in protocols and devices used around the world. Commonly used and reliable measures are voluntary protocols performed on a computerized dynamometer. However, these voluntary measurements might also be influenced by external factors as patients effort or motivation. Therefore, it is important to evaluate the relation between voluntary and involuntary (i.e. electrical stimulated) assessed quadriceps muscle endurance.

Study objective

The primary objective is to assess the relation between involuntary and voluntary assessed quadriceps muscle endurance in patients with COPD.

Study design

Cross-sectional observation study.

Study burden and risks

BURDEN: All measurements are part of standard care, except for one questionnaire and (involuntary) electrical assessed quadriceps function. Thus, the additional burden for the patient is one additional measurement of approximately 70 minutes.
RISKS: Performance of electrically evoked assessment of muscle function is not associated with a health risk. This procedure is non-invasive and not painful and performed routinely at the department of Physiology (Radboudumc, Nijmegen). Therefore, no safety risk is involved.
BENEFIT: The benefits will be high as it will provide more insight in the relation between voluntary and involuntary assessed quadriceps muscle endurance. This insight is necessary to optimize the clinical assessment of muscle endurance in patients with COPD.
GROUP RELATEDNESS: This will be the first study in which the relation between voluntary and involuntary assessed quadriceps muscle endurance in COPD will be investigated. These results will also be valuable for other diseases/conditions in which isolated muscle endurance should be assessed like asthma, pulmonary hypertension, etc.

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

• COPD, based on GOLD classification
• Clinically stable according to the pulmonary physician, i.e. no exacerbation and/or hospitalization within the previous 4 weeks
• Age between 40-80 years

Exclusion criteria

• Inability to understand the Dutch language
• Musculoskeletal and neurological problems influencing quadriceps muscle function testing

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):	05-07-2022
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	25-04-2022
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	NL80842.091.22