Pilot study in gait perturbations in patients with chronic obstructive pulmonary disease

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The primary objective is to determine if patients with chronic obstructive pulmonary disease (COPD) have an altered adaptation potential of the reactive stepping response following repeated mechanical perturbations while walking.

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

Summary

ID

NL-OMON45605

Source
ToetsingOnline

Brief title
Gait perturbations in COPD

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic bronchitis, chronic obstructive pulmonary disease (COPD), emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Ciro
Source(s) of monetary or material Support: Ciro

Intervention

Keyword: COPD, Dynamic balance, Gait, Perturbations

Outcome measures

Primary outcome

The main study parameter is the reactive adaptation potential measured during the locomotor plasticity assessment protocol with the Gait Real-time Analysis Interactive Lab. This will be calculated as the magnitude of change in the margin of stability at touchdown of the first step after the perturbation before and after repetition of the perturbation.

Secondary outcome

Walking speed, step width, step length, cadence at touchdown of the first and following recovery steps after each perturbation.

Study description

Background summary

Patients with chronic obstructive pulmonary disease (COPD) show balance disturbances in contrast to healthy peers. In addition, patients with COPD have an increased risk for falls. Falls usually ocuur during walking and are often attributed to age-related neuromuscular deficiences, for example reduced muscle strength. The ability to react and take a large, balance recovery step following perturbations (e.g. trip, slip or stumble) is an important factor in recovering from mechanical perturbations. However, recovery stepping responses are diminished in older subjects and might be affected even more in patients with COPD due to systemic effects of the disease. Consequently, a pilot study will be conducted to gain insight in the consequences of COPD on the adaptation potential and initial recovery response to mechanical perturbation.

Study objective

The primary objective is to determine if patients with chronic obstructive pulmonary disease (COPD) have an altered adaptation potential of the reactive

stepping response following repeated mechanical perturbations while walking.

Study design

This study is an observational pilot study

Study burden and risks

Participation in the pilot study will require one visit to Ciro (flexible depending on availability of subjects) with a time commitment including all measurements of between 1.5 and 2 hours.
All subjects will undergo measurements of their height and weight.
The first familiarisation session on the treadmill will take maximal 9 minutes.
After a period of rest, the second familiarisation session will take maximal 13 minutes.
After a period of rest, the gait perturbation protocol will take about 15 minutes.

The treadmill sessions could be fatiguing and subjects need to familiarize with treadmill walking. A subject's balance could be disturbed during the gait perturbation protocol. However, additional safety measures are taken: a subject will wear a safety harness, the system has one emergency switch in case subjects tend to walk past the treadmill safety zone, there is a manual safety switch to terminate the treadmill trial, there is CPR emergency button in the room in which the data are collected, subjects will conduct two treadmill familiarisation sessions prior to the gait perturbation protocol in order to accustom to the treadmill. Finally, the researcher, a certified GRAIL operator, will direct the subject during the measurements.

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

Older healthy adults:
- Healthy subjects
- Aged between 50-80 years old
- No known musculoskeletal disease, condition or injury that could negatively affect walking or balance ability
- No history of balance problems, dizziness or walking difficulties
- Must be able to walk at comfortable speed for 30 minutes without stopping
- Informed consent given;Patients with COPD
- Main diagnosis is COPD, diagnosed at CIRO (FEV1/FVC <0.70)
- Aged between 50-80 years old
- Must be able to perform the 6-minute walk test without a stop and without the use of walking aids
- Must be stable: no exacerbation of COPD, defined as an acute event characterized by a worsening of the patient*s respiratory symptoms that is beyond normal day-to-day variations and leads to a change in medication, within 4 weeks to data collection
- No chronic oxygen use
- Informed consent given

Exclusion criteria

- musculoskeletal disease, condition or injury
- subject is unable to walk without walking aids
- subject is unable to perform the 6-minute walk test without a stop
- subject with open wounds
- subject with balance problems, dizziness or walking difficulties (for healthy older adults)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-10-2018
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	28-07-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-12-2019
Application type:	Amendment
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	NL61317.100.17
Other	Onderzoek wordt geregistreerd zodra goedkeuring is ontvangen (op www.trialregister.nl)

Study results

Date completed:	04-06-2019
Actual enrolment:	24