Effects of swallowing therapy for dysphagia on exacerbations of Chronic obstructive pulmonary disease

Published: 05-09-2018
Last updated: 10-04-2024

The aim of this study is to evaluate the effect of a swallowing treatment program on the frequency of COPD exacerbations in the COPD gold II-IV patient groups. The secondary objective is to evaluate the possible improvement in swallowing function.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Interventional

Summary

ID

NL-OMON50180

Source
ToetsingOnline

Brief title
Effects of swallowing therapy for dysphagia on exacerbations of COPD

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Chronic bronchitis, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: stichting Wijjocha

Intervention

Keyword: COPD, dysphagia, exacerbations, swallowing therapy

Outcome measures

Primary outcome

The primary outcome measure is the number of moderate to severe exacerbations over a period of 12 months after allocation to treatment or control group. An exacerbation is defined as moderate if treatment with antibiotics or corticosteroid is initiated or dosage increase should be given. An exacerbation is defined as severe if a patient had to be hospitalized because of the exacerbation or dies.

Secondary outcome

The secondary outcome measure is patient swallowing satisfaction measured by the VAS (visual analog scale) and the dysphagia disability index. These are evaluated at baseline and after 12 months

Study description

Background summary

Chronic obstructive pulmonary disease (COPD) is characterized by progressive non-reversible airway constriction. There are four stages of COPD, Gold 1 to 4. The severity of disease increases by ascending COPD gold level. Exacerbations or lung attacks in COPD patients cause morbidity, hospitalization and mortality and greatly affect the quality of life of these patients. Dysphagia increases the risk of exacerbations in COPD patients. The dysphagia is often not perceived by patients. Treatment of swallowing disorders and improvement of swallow coordination improves the quality of swallowing and possibly reduces the number of exacerbations.

Study objective

The aim of this study is to evaluate the effect of a swallowing treatment program on the frequency of COPD exacerbations in the COPD gold II-IV patient groups. The secondary objective is to evaluate the possible improvement in swallowing function.

Study design

single-blind controlled intervention study

Intervention

swallow therapy

Study burden and risks

There are varying time burdens associated with group allocation. The time burden will range from two to ten sessions at the rehabilitation center or via video calls. Additionally home exercise compliance is expected from group 1. The intervention could theoretical cause choking with possible pneumonia and exacerbations as a consequence, because participants have not mastered the new techniques immediately. However, in the therapeutic setting, water will be used to practice and progressing to other consistencies will only take place when participants display competent water swallowing techniques. Other side effects are not known.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• COPD gold 2,3,4 with a Pulmonary Function Testing not older than 12 months
• At least 2 proven moderate or severe COPD exacerbation in the last 2 years

Exclusion criteria

other lungdisease
active exacerbation COPD
reduced learning because of congnitive impairment
recent speech therapy (< 2 years)
other cause for dysphagia
Radiation of the mouth and throat area
Operation of the mouth and throat area
severe language barrier

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-06-2019
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	05-09-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-09-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Not approved Date:	13-09-2023
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	NL62277.101.18