Introduction in the NEtherlands of the Vapor treatment for patients with severe Emphysema: a new Lungvolume reduction treatment

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The overall aim of this study is to gain experience with the Thermal Vapor treatment by investigating the safety and efficacy of the treatment.Primary Objective: The primary objective is to investigate the change in Lung function (measured by Forced…

Ethical review	Approved WMO
Status	Will not start
Health condition type	Respiratory disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON49289

Source
ToetsingOnline

Brief title
NEVEL-study

Condition

- Respiratory disorders NEC

Synonym
COPD, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Unrestricted grant van de fabrikant van het hulpmiddel.,Uptake medical

Intervention

Keyword: Bronchoscopy, COPD, Emphysema, Vapor

Outcome measures

Primary outcome

The primary objective is to investigate the change in Lung function which will

be measured by Forced Expiratory Volume in 1 second (FEV1) between baseline and

6 months after the Thermal Vapor treatment.

Secondary outcome

Safety will be assessed by:

The number and type of treatment- related adverse events during 1 years follow

up after complete treatment.

Efficacy & long term follow up will be assessed by:

The change in Lung function, lung hyperinflation, quality of life, dyspnea, CT

parameters and exercise capacity between baseline and 6 and 12 months follow up

after treatment. Longterm efficacy will be investigated up to 5 year follow up

after treatment.

Lung function: Spirometry and Bodyplethysmography

Quality of Life: St. George*s Respiratory Questionnaire (SGRQ) and COPD

Assessment test (CAT) questionnaire

Dyspnea : modified Medical Research Council Scale

CT parameters: Quantitative CT analyses

Exercise capacity: 6-minute walk distance test (year 1-3-5)

Study description

Background summary

The STEP-UP trial investigated the bronchoscopic lung volume reduction treatment using vapor and showed that the treatment group significantly improved after 6 months compared to the control group in Lung function and quality of life. The authors also concluded that the treatment has an acceptable safety profile. The results of this trial has led to the inclusion of this treatment in the COPD GOLD guidelines in 2019. In the Netherlands the treatment has not been performed so far but the treatment device has been made available to the UMCG hospital to perform emphysema treatments. Yearly, approximately 600 severe emphysema patients are referred to the UMCG for a bronchoscopic treatment but only approximately 10% is suitable for a treatment with endobronchial valves or coils. Some of the other patients could benefit from the Vapor treatment and therefore with this treatment we will be able to treat patients who have no other treatment options left.

Study objective

The overall aim of this study is to gain experience with the Thermal Vapor treatment by investigating the safety and efficacy of the treatment.

Primary Objective:
The primary objective is to investigate the change in Lung function (measured by Forced Expiratory Volume in 1 second (FEV1)) between baseline and 6 months after the Thermal Vapor treatment.

Secondary Objectives:
Safety
* A secondary objective is to investigate the safety of the Thermal Vapor treatment by recoding all the adverse events that occur between baseline and 1 year follow up after treatment.
Efficacy
* A secondary objective is to investigate the change in Lung function, lung hyperinflation, quality of life, dyspnea, CT parameters and exercise capacity between baseline and 6 and 12 months follow up after treatment.
Longterm
* A secondary objective is to investigate the long term effect of the treatment in terms of change in Lung function, lung hyperinflation, quality of life and exercise capacity between baseline and up to 5 years follow up after treatment.

Study design

This study will be a prospective observational, single center study that will investigate the safety and efficacy of the InterVapor (Bronchoscopic Thermal Vapor Ablation System) that will be introduced in the Netherlands for the first time. All patients that undergo the bronchoscopic lung volume reduction treatment using thermal Vapor will be asked if their data can be captured in the database.

Study burden and risks

The extra tests that will be performed as part of this study are 1 low dose CT scan and 2 times peripheral blood collection and bronchial wash collection before treatment(s) and all data will be registered in a database to be able to evaluate the efficacy and safety of the treatment. These are procedures for which the risks are low.

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. Patient is scheduled for a bronchoscopic lung volume reduction treatment using Thermal Vapor
2. Read, understood and signed the Informed Consent form.

Exclusion criteria

There are no exclusion criteria for this study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	24
Type:	Anticipated

Ethics review

Approved WMO

Date:	12-02-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT04029077
CCMO	NL70894.042.19