Ventilator-associated injury (VAI) in chronic home mechanical ventilation: a paradigm switch in order to improve ventilatory support

Published: 05-08-2020
Last updated: 19-08-2024

The primary aim of the study is to get insight in the effects of long-term HI-NIV in severe COPD patients on the respiratory muscles; i.e. the contractile strength and the structure of single diaphragm and intercostal muscle fibres and the lungs; i....

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

Summary

ID

NL-OMON49038

Source
ToetsingOnline

Brief title
VAI-HMV

Condition

- Bronchial disorders (excl neoplasms)

Synonym
COPD

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic Obstructive Pulmonary Disease, Noninvasive ventilation, Respiratory muscles, Ventilator induced lung injury

Outcome measures

Primary outcome

The study is an exploratory pilot study. We will investigate both contractile strength and the structure of single diaphragm and intercostal muscle fibres as well as lung injury; i.e. alveolar structure and damage and inflammation in the alveoli.

Secondary outcome

The study is an exploratory pilot study. We will investigate both contractile strength and the structure of single diaphragm and intercostal muscle fibres as well as lung injury; i.e. alveolar structure and damage and inflammation in the alveoli.

Study description

Background summary

Chronic Obstructive Pulmonary Disease (COPD) is a progressive inflammatory disease characterised by airway and lung parenchyma damage. At end-stage disease patients may develop chronic hypercapnic respiratory failure. The underlying process for this is incompletely understood and the role of respiratory muscle alterations is unclear. Home noninvasive ventilation with high-intensity ventilatory settings (HI-NIV) has been shown to be effective in these severe COPD patients. However, in patients being mechanically ventilated on the intensive care unit for diverse reasons, high-intensity ventilation, especially high tidal volumes, has been shown to result in ventilator associated lung and diaphragm injury. Whether this occurs in home

high-intensity NIV, is however completely unknown.

Study objective

The primary aim of the study is to get insight in the effects of long-term HI-NIV in severe COPD patients on the respiratory muscles; i.e. the contractile strength and the structure of single diaphragm and intercostal muscle fibres and the lungs; i.e. alveolar structure and damage and inflammation, by comparing COPD patients that had been treated with long-term NIV to patients that were not treated with long-term NIV prior to lung transplantation. Because respiratory muscle functioning, lung mechanics and clinical characteristics, although patients all suffer from end-stage disease, are completely different in COPD compared to for example advanced stage pulmonary fibrosis, we will, as a secondary aim, compare the observed changes in respiratory muscle morphology of COPD patients with respiratory muscle morphology of patients with pulmonary fibrosis.

Study design

In order to investigate this, we will include in a small pilot cohort study patients being lung transplanted. In these patients there is lung tissue available and respiratory muscle biopsies will be performed during lung-transplant surgery.

Study burden and risks

The burden of the participants is limited. For study purposes, additional investigations are performed shortly before and during the lung transplant procedure, consisting of an additional blood sample taken, a broncho-alveolar lavage just prior before the lung are taken out and respiratory muscle biopsies (of the diaphragm and intercostal muscles) during the surgery. The procedures performed to investigate lung architecture are performed in the explanted lungs. Patients will not be asked to perform additional tests. The additional procedures performed are not expected to have side-effects or risks.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700RB
NL
Scientific

Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. RLD: probable or confirmed diagnosis of interstitial pulmonary fibrosis (IPF) or other fibrotic lung disease of unknown origin.
2. COPD: GOLD stage III or IV
3. Being listed for lung transplantation

Exclusion criteria

1. Concomitant neuromuscular or systemic/collagen-vascular disease
2. Prior lung surgery or lung volume reduction treatment
3. Being unable to understand the patient information and consent for the study

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2020
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	05-08-2020
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	NCTvolgt
CCMO	NL74163.042.20