Resmon Pro Diary Pilot Study - Evaluation of Vivisol Service to remotely prevent COPD exacerbations

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pulmonary vascular disorders
Study type	Interventional

Summary

ID

NL-OMON49847

Source
ToetsingOnline

Brief title
Resmon Pro Diary Pilot Study

Condition

- Pulmonary vascular disorders

Synonym
chronic bronchitis, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: VIVISOL NL
Source(s) of monetary or material Support: VIVISOL Nederland draagt de kosten voor de pilot

Intervention

Keyword: COPD, MONITORING, Resmon, VIVISOL

Outcome measures

Primary outcome

The goal is to define the best practices for the introduction of the home

monitoring with Resmon Pro Diary in the Dutch clinical practice.

Secondary outcome

Secondary objectives are:

To gain insight about:

- The quality of the data communication, and the information obtained

- The procedure: is it the ideal workflow to achieve the desired results?

Study description

Background summary

The Netherlands has a high burden of Chronic Obstructive Pulmonary Disease (COPD) due to premature morbidity, loss of healthy life years, high mortality and high economic and societal costs. During the course of the disease it may happen that a general deterioration with an increase in symptoms occurs. This usually occurs due to a respiratory infection. This exacerbation can be characterized as mild, moderate or severe.
The exacerbation can lead to hospitalization. A severe exacerbation can have a slow recovery, may lead to a permanent impairment or decrease in FEV including a decline in QOL. In addition to these negative effects on the patient, exacerbations also increase the costs for the society. It is therefore of utmost importance to detect a possible exacerbation at an early stage so that with a timely intervention it is possible to avoid hospitalization.
Thanks to the Resmon Pro Diary it is now possible to early detect patient worsening, giving the physician the possibility to act efficiently in order to avoid the exacerbation or reduce its severity. It consists of a unit that is placed at the patient home, a 3G sim card and a data server that communicates with Vivisol.
Resmon PRO Diary is a device with which no treatment is given, it is intended

to monitor remotely COPD patients at home. Patients do not have to perform forced maneuvers. The patient only has to breathe through the device for 15 normal respiratory acts. The device automatically discards cough events and incorrect breaths. No supervision is needed after the first training. No risks or adverse effects were observed in previous studies.

Study objective

This pilot does not aim to demonstrate the effectiveness of the system. The effectiveness of the system has been demonstrated in the recently published study: Chromed study, a multi-center Randomized Controlled Study.
This pilot aims to obtain information about how Vivisol's service with the Resmon Pro Diary is experienced in Dutch practice, by both the clinician/ health care providers and patients.

Study design

The study can be divided in the following steps:
1. The Hospital selects 3 COPD patients fulfilling the inclusion criteria.
2. The patient receives the outpatient information about the pilot study and signs an informed consent.
3. The patient is visited by Vivisol at home and hereby receives a Resmon Pro Diary.
4. Patient signs an agreement that Vivisol can monitor the data from the Resmon Pro Diary via telemonitoring.
5. Patient breathes normally every day for 15 respiratory acts in the Resmon Pro Diary. The test need to be done every day at the same time, for example before taking any medications.
6. The patient will respond to a questionnaire 3 weeks after the beginning of the pilot and again during the 3rd month of the trial. THe physician has to fill out a questionnaire 3 months after the start of the trial.
7. After 12 months, the pilot is terminated and Vivisol retrieves the Resmon Pro Diary.
8. At the end of the pilot the patient and physician has to fill out a brief questionnaire .

Three hospitals will be selected to participate in this pilot study. Each hospital will select 3 patients for this pilot study. The 9 patients will be in the study for 12 months.

Intervention

Patients have to breath normally in the Resmon Pro Diary 15 times a day. Vivisol will monitor the patient daily form a distance and will inform the physician as soon as the Resmon Pro Diary predicts an exacerbation. The

physician is responsible for further follow-up with the patient.

Study burden and risks

Burden for the patient:
- Daily breathing in the Resmon Pro Diary (15 breaths - 90 seconds every day)
- 3 questionnaires (total 10 minutes)

Risks: none

Contacts

Public
VIVISOL NL

Swaardvenstraat 27
Tilburg 5048 AV
NL
Scientific
VIVISOL NL

Swaardvenstraat 27
Tilburg 5048 AV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

COPD patients > 18 years old
Belonging to Gold stages II, III or IV
In the year prior to the pilot, at least one exacerbation that has led to a hospitalization.

Exclusion criteria

All patients not covered by the inclusion criteria
Patients who are unable or not willing to use the device autonomously

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-04-2021
Enrollment:	9
Type:	Actual

Medical products/devices used

Generic name:	Resmon Pro Diary
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	02-04-2020
Application type:	First submission

Review commission: METC Isala Klinieken (Zwolle)

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	NL71753.075.19