Triple therapy convenience by the use of one or multiple inhaler and digital support in Chronic Obstructive Pulmonary Disease

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON51328

Source
ToetsingOnline

Brief title
TRICOLON

Condition

- Respiratory disorders NEC

Synonym
Chronic obstructive pulmonary disease (COPD)

Research involving
Human

Sponsors and support

Primary sponsor: Franciscus Gasthuis & Vlietland

Source(s) of monetary or material Support: Chiesi Farmaceutici,Chiesi Pharmaceuticals BV;DSW + transformatiegelden en eigen inbreng onderzoeksgroep

Intervention

Keyword: Adherence, COPD, E-health

Outcome measures

Primary outcome

Average adherence to inhalation therapy (expressed in a percentage, measured as

the number of actuations registered by the e-device divided by the total dose)

over 12 months of treatment

Secondary outcome

Changes in TAI questionnaire score, beclomethasone and/or formoterol

accumulation profile in hair analysis and differences in clinical outcomes and

Patient Reported Outcome Measures (PROM*s), such as the Clinical COPD

Questionnaire (CCQ), number of exacerbations and Salbutamol use

Study description

Background summary

Chronic obstructive pulmonary disease (COPD) is a common, chronic lung disease and is associated with high morbidity and mortality. Pharmacologic treatment often involves multiple classes of inhaled medication that have been proven effective in clinical trials. However, the effectiveness of treatment with inhaled medication in the real-world is strongly influenced by medication adherence. In previous studies, it was shown that adherence rates in COPD patients are low and that nonadherence is related to poor clinical outcomes. Nonadherence is caused by many different factors, including the type of inhaler device(s) being used. Notably, the use of multiple different types of inhalers could increase the risk of inhaler errors and poor adherence. Our hypothesis is that simplifying the treatment by single-inhaler triple therapy instead of multi-inhaler triple therapy will positively influence the adherence to inhalation medication. Furthermore, we hypothesize that the adherence improves

if patients use an e-device with feedback system and supportive e-health platform.

Study objective

The primary objective of this study is to investigate if single-inhaler triple therapy (SITT, in this study Trimbow®) is superior to multi-inhaler triple therapy (MITT, in this study Bevespi® and Qvar®) in terms of adherence to inhaled corticosteroids (ICS) therapy (average adherence measured by an e-device) over 12 months of treatment and to investigate if SITT with e-health support is superior to MITT and SITT without e-health support in terms of adherence to ICS therapy.

Secondary objectives are:
- Validation techniques to measure adherence: actuations e-device vs TAI questionnaire vs hair analysis (beclomethasone and/or formoterol)
- to investigate link between adherence and clinical outcomes.
- to investigate if the adherence after a recent exacerbation differs from the adherence during stable disease

Study design

The study is a investigator initiated, prospective, interventional, open-label, randomized, real-world, multi-centre, 3-arms study

Intervention

The first group will receive multi-inhaler triple therapy (control group), the second group single-inhaler triple therapy (intervention group 1) and the third group single-inhaler triple therapy with extra digital support to increase therapy adherence (intervention group 2). The digital support consists of an e-device connected to an app and e-health platform, including reminders, extra insight in disease progression and e-consults with the healthcare practitioner

Study burden and risks

In usual care, COPD patients visit the hospital three times each year. The visits for this study are simultaneously with the standard care, however spending a longer time in the hospital for completing questionnaires, lung function and hair donation can be cumbersome to the patients. They will be asked to fill out nine questionnaires/scores at three different time points, will be submitted to a lung function two times and hair will be collected at one occasion.
All patients will receive triple therapy. The patients included in this study are indicated to standard care triple therapy and consequently not subject to additional side effects, discomfort or risks. The use of the app may be

experienced as burdensome by patients, but is expected to be not very stressful. The study will have as little as possible further interventions, in order not to influence medication adherence and make the study most comparable to the real world.

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

• Clinical diagnosis of COPD for at least 1 year before the screening visit
• Aged 40 years and older
• An indication for triple therapy according to the investigator*s judgement (following the GOLD guideline 2021(2)).
Could be step-up from dual therapy or currently receiving triple therapy (both MITT and SITT).

• Owner of mobile device compatible with e-device app with access to internet (Android or iOS)
• Willing to provide written informed consent
• Current or ex-smoker

Exclusion criteria

• Inability to comply with study procedures or with study treatment
• Inability to speak and/or read Dutch
• Asthma as the predominant disease according to the investigator*s opinion, a past history of asthma is allowed
• Use of e-health application for COPD in the past six months
• Patients with any other therapy that could interfere with the study drugs (according to the investigator*s opinion)
• Use of nebulized bronchodilators, for example via pari boy
• Pregnant or lactating women and all women physiologically capable of becoming pregnant unless they have highly effective contraceptive
• Patients mentally or legally incapacitated, or patients accommodated in an establishment as a result of an official or judicial order
• Patients without the capability to complete the questionnaires

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-12-2022
Enrollment:	300
Type:	Actual

Medical products/devices used

Generic name:	Smart inhaler/e-device
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-05-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-08-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-11-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-03-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-08-2024
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	NL79938.100.22