Triple therapy effectiveness in COPD patients with characteristics of asthma: A pragmatic primary care trial - The TRACkER trial

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It is expected that patients in the triple therapy group improve their health status (CCQ score) more than the patients in the LABA/LAMA group.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28851

Bron
Nationaal Trial Register

Verkorte titel
TRACkER

Aandoening

COPD

Ondersteuning

Primaire sponsor: GPRI
Overige ondersteuning: Chiesi Pharamceuticals B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To investigate the effectiveness of triple therapy (ICS/LABA/LAMA) on the change in health status, measured with the Clinical COPD Questionnaire (CCQ), in symptomatic ICS-naive COPD patients with characteristics of asthma according to GOLD 2019 (age of onset, pattern of respiratory symptoms, history/family of asthma, history of Atopy) and blood eosinophil counts of ≥100 cells per µL compared to treatment with dual therapy (LABA/LAMA), within a primary care population. Effectiveness is regarded as difference in the proportion of patients a with minimal clinically improvement on health status (CCQ improvement ≥0.4) between the study groups.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: (Inter)National guidelines identify several patient characteristics that can be used to select patients with Chronic Obstructive Pulmonary Disease (COPD) who may benefit from inhaled corticosteroids (ICS) containing treatment. These characteristics include asthma characteristics, high blood eosinophil (Eos) counts and frequent exacerbations (despite the usage of a bronchodilator). However, this evidence was originally based on post hoc analysis from randomised controlled trials. Little is known regarding the utility of these characteristics in real life, as tools for guiding doctor’s decision to prescribe ICS containing medication in routine practice.

Objective: To investigate the effectiveness of triple therapy (ICS/ long-acting beta 2 agonist (LABA)/long-acting muscarine antagonist (LAMA)) on the change in health status, measured with the Clinical COPD Questionnaire (CCQ), in symptomatic ICS-naive COPD patients with characteristics of asthma according to GOLD 2019 and blood eosinophil counts of ≥100 cells per µL compared to treatment with dual therapy (LABA/LAMA), within a primary care population. Effectiveness is regarded as difference in the proportion of patients with a minimal clinically improvement on health status (CCQ improvement ≥0.4) between the study groups.

Study design: This is a prospective, real-life, randomised controlled trial of 26 weeks, which is conducted in general practices in the north of the Netherlands comparing triple therapy (ICS/LABA/LAMA) with dual bronchodilator treatment (LABA/LAMA). We aim to randomise 316 patients. Patients will be randomized (1/1) either to the triple therapy arm or the LABA/LAMA treatment arm.

Study population: ICS-naive symptomatic (CCQ≥1) primary care COPD patients aged over 40 years who are currently using one or two long-acting bronchodilators with characteristics of asthma (age of onset <20 years; day to day variation in symptoms or symptoms which are worse during the night/early morning; history of asthma, allergy, rhinitis, eczema) and a blood eosinophil count of ≥100 cells per µL.

Intervention: In the intervention group patients will use a single inhaler triple therapy (Trimbow), which includes a combination of beclomethasone dipropionate, formoterol

fumarate dihydrate, and glycopyrronium bromide. This inhaler is used twice a day. In the control group patients will use dual bronchodilator treatment (LABA/LAMA) which is used according to the prescription.

Main study parameters/endpoints: The primary outcome of this study is the difference in the proportion of patients with a clinically relevant improvement in health status (≥0.4 improvement on the CCQ) between the triple therapy group and LABA/LAMA treatment groups at the end of the 26 weeks intervention period. All main analyses will be conducted intention-to-treat.

Doel van het onderzoek

It is expected that patients in the triple therapy group improve their health status (CCQ score) more than the patients in the LABA/LAMA group.

Onderzoeksopzet

Study start: 02-12-2019
Start inclusion: 16-12-2019
Study period: 26 weeks/6 months
End inclusion period: 01-07-2019

Onderzoeksproduct en/of interventie

In the intervention group patients will use a single inhaler triple therapy (Trimbow), which includes a combination of beclomethasone dipropionate, formoterol fumarate dihydrate, and glycopyrronium bromide. This inhaler is used twice a day. In the control group patients will use dual bronchodilator treatment (LABA/LAMA) which is used according to the prescription.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Physician diagnosis of COPD (documented obstruction or obstruction measured at the first study visit)
- Age 40 years and older
- Symptomatic (defined as Clinical COPD Questionnaire score ≧ 1)
- ICS-naive (last 12 months no ICS containing treatment)
- Usage of a long-acting bronchodilator; either usage of a single LABA or LAMA, usage of a single LABA and a single LAMA, or a usage of a single LABA/LAMA inhaler. Patients are allowed to use short-acting bronchodilator.
- Blood eosinophils ≥100 cells per µL
- One or more characteristics of asthma according to GOLD 2019 (age of onset, pattern of respiratory symptoms, history/family of asthma, history of Atopy).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Chronic oral corticosteroid, use more than 60 days in the last 3 months
- Recent exacerbation (last 6 weeks before inclusion)
- Life expectancy of less than 2 years
- Allergy to intervention formulation
- Inability to understand Dutch
- Any other condition which, at the GPs and/or investigator’s discretion, is believed to present a safety risk or may impact the study results
- Patients participating in another ongoing clinical trial that in the investigator’s opinion influences the current study (e.g. another randomized controlled trial)
- In ability to understand and sign the written consent form.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	02-12-2019
Aantal proefpersonen:	316
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
The researchers can be contacted to discuss the details of sharing the data.

Ethische beoordeling

Positief advies

Datum:	11-12-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54789
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8227

Register	ID
CCMO	NL71310.056.19

Resultaten