Vasco da Gama

Gepubliceerd: 06-07-2020 Laatst bijgewerkt: 18-08-2022

We hypothesize that long-term continuation of macrolide maintenance therapy after at least 1 year of treatment in COPD patients results in a prolonged time to next exacerbation compared to withdrawal of azithromycin macrolide treatment

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

Samenvatting

ID

NL-OMON24560

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

COPD

Ondersteuning

Primaire sponsor: M.J.J.H. Grootenboers
Overige ondersteuning: Wetenschapsfonds Amphia Ziekenhuis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

·To assess the time to first exacerbation of COPD, measured from the time of randomization

Toelichting onderzoek

Achtergrond van het onderzoek

Chronic obstructive pulmonary disease (COPD) is characterized by small airway disease and parenchymal destruction. Acute exacerbations of COPD (increased cough, dyspnoea and/or increased sputum) are associated with increased mortality and worsening of COPD and/or level of health. Inhalation therapy with long acting antimuscarinic agents (LAMA), long acting β agonists (LABA) and inhaled corticosteroid-LABA combination inhalers significantly reduces AECOPD. Nonetheless a selection of patients still experience frequent exacerbations. In this group The Columbus study showed that macrolide maintenance therapy resulted in a decreased exacerbation frequency . However, macrolide resistance and adverse effects are of great concern.
The duration of macrolide maintenance therapy has not been studied yet. Studies were performed with a follow up period of a maximum period of one year. There is no information available about the value of azithromycin maintenance treatment for more than one year.
Study design: Prospective randomized placebo controlled, single center trial comparing an intervention group (continuation of azithromycin maintenance treatment) with a control group (withdrawal of azithromycin).
Study population: Stable COPD with maintenance macrolide treatment

Doel van het onderzoek

We hypothesize that long-term continuation of macrolide maintenance therapy after at least 1 year of treatment in COPD patients results in a prolonged time to next exacerbation compared to withdrawal of azithromycin macrolide treatment

Onderzoeksopzet

t=0 (inclusion), t=3, 6 and 9 months (first evaluations), t=12 months (end-evaluation)

Onderzoeksproduct en/of interventie

withdrawal of azithromycin macrolide treatment

Contactpersonen

Publiek

Amphia
Sander Talman

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Wetenschappelijk

Amphia
Sander Talman

0765955351

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Diagnosis of COPD according to GOLD 2019 definition
Exacerbation > 28 days before inclusion
Age ≥ 18 years
Azithromycin maintenance therapy for at least one year preceding the start of the trial and initially started because of frequent exacerbations (≥3 a year)
Clinical stable COPD with azithromycin maintenance, determined as 2 or less exacerbations during the year before randomization
Informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Use of antibiotics or high dose of systemic steroids within a month prior to involvement in the study
Addition of inhalation steroids to the patient's therapy regimen, <28 days before entering the study.
Pregnant or lactating women.
Liver disease (alanine transaminase and/or aspartate transaminase levels 2 or more times the upper limit of normal).
Asthma, defined as episodic symptoms of airflow obstruction which is reversible with bronchodilators, assessed with lung function testing.
Presence of a malignancy, which is clinically active.
Bronchiectasis.
Heart failure.
Use of drugs which can adversely interact with macrolides and for which therapeutic monitoring cannot be undertaken

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	64
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	06-07-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8761
Ander register	METC EMC : MEC-2019-0838

Resultaten