Vasco da Gama

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24560

Source
NTR

Brief title
TBA

Health condition

COPD

Sponsors and support

Primary sponsor: M.J.J.H. Grootenboers
Source(s) of monetary or material Support: Wetenschapsfonds Amphia Ziekenhuis

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

To evaluate the improvement of quality of life by Saint George’s Respiratory Questionnaire;
To evaluate pulmonary function (FEV1)
To evaluate the frequency of exacerbation requiring an intervention with systemic

corticosteroids and antibiotics (oral/intravenous [i.v.]) in subjects with COPD.
To assess the microbiology of sputum production
To assess the safety and tolerability of long term azithromycin
To assess the inflammatory response measured by the following inflammatory markers: high-sensitivity C-reactive protein, the erythrocyte sedimentation rate, polymorphonuclear leukocytes, neutrophils; eosinophils; interleukin-6, interleukin-8, and myeloperoxidase;

Study description

Background summary

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

Study objective

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

Study design

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

Intervention

withdrawal of azithromycin macrolide treatment

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	64
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	06-07-2020
Application type:	First submission

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
NTR-new	NL8761
Other	METC EMC : MEC-2019-0838

Study results