Defining long-term macrolide maintenance therapy in COPD: a single center randomized controlled trial:

Published: 09-06-2020
Last updated: 17-01-2025

The primary objectives of this study are:· To assess the time to first exacerbation of COPD, measured from the time of randomization The secondary objectives of this study are:· To evaluate the improvement of quality of life by Saint George*s...

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

Summary

ID

NL-OMON49192

Source
ToetsingOnline

Brief title
Vasco da Gama

Condition

- Respiratory disorders NEC

Synonym
chronic bronchitis, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: amphia

Intervention

Keyword: COPD, Duration, Exacerbation, Macrolide

Outcome measures

Primary outcome

time to first exacerbation of COPD, measured from the time of randomization

Secondary outcome

improvement of quality of life by Saint George*s Respiratory Questionnaire;

pulmonary function (FEV1)

frequency of exacerbation requiring an intervention with systemic

corticosteroids and antibiotics (oral/intravenous [i.v.]) in subjects with

COPD.

microbiology of sputum production

safety and tolerability of long term azithromycin

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 increase 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 exacerbation. 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 objective

The primary objectives of this study are:
· To assess the time to first exacerbation of COPD, measured from the time of randomization

The secondary objectives of this study are:
· 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

Further objectives include:
· 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 design

Double blind randomized placebo controlled single center trial

Intervention

Randomizing in either continuation of macrolide maintenance therapy or withdrawal of maintenance therapy

Study burden and risks

Randomizing into the placebo group could hypothetically mean that exacerbation is increasing, but we consider this chance extremely low.The blood test can cause local pain and bruising.The lung function test and the 6-minute walk test

are without danger, there may be some fatigue. Sputum culture / throat culture, no known risks

Contacts

Public
Amphia Ziekenhuis

Molengracht 21
Breda 4818CK
NL
Scientific
Amphia Ziekenhuis

Molengracht 21
Breda 4818CK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

COPP patients with azithromycin maintenance therapy for at least 12 months and who have a stable exacerbation rate (2 or less exacerbations a year).
The initial indication for azithromycin maintenance therapy is frequent exacerbations (3 or more exacerbations a year)

Exclusion criteria

Bronchiectasis
Asthma
Antibiotics and prednisolon treatment because of an exacerbation in the last month
prednisolone maintenance more than 5mg a day

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-05-2021
Enrollment:	64
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Azithromycin
Generic name:	Azithromycin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Placebo
Generic name:	Placebo

Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	09-06-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-06-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-01-2025
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2019-004178-24-NL
CCMO	NL71864.078.19