Doxycycline and airway inflammation in COPD
A randomised placebo controlled cross-over trial in patients with GOLD III COPD

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To assess the effect of low dose doxycycline on markers of neutrophilic inflammation and proteolytic activity stable GOLD III COPD patients.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON31738

Source
ToetsingOnline

Brief title
Doxycycline and airway inflammation in COPD

Condition

- Bronchial disorders (excl neoplasms)

Synonym
COPD, lung emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: Nog niet duidelijk.

Intervention

Keyword: COPD, doxycycline, inflammation, MMP

Outcome measures

Primary outcome

Change in sputum IL-6 levels

Secondary outcome

Change in FEV1

Change in markers of neutrophil activation/activity (IL-8, MMP-8, MMP-9 and

MPO), T cell activation (granzyme A and perforin) and monocyte activation

(TNF-α, IL-1, cathepsin K

Study description

Background summary

COPD is a disease characterized by chronic inflammation and irreversible airway obstruction. Chronic inflammation lead to degradation of extracellular matrix and hereby destruction of lung parenchyma. Tetracyclines are known for their anti-inflammatory properties in diseases such as rheumatoid arthritis.

Study objective

To assess the effect of low dose doxycycline on markers of neutrophilic inflammation and proteolytic activity stable GOLD III COPD patients.

Study design

Placebo versus doxycycline in a cross-over design

Intervention

Doxycycline vs placebo

Study burden and risks

None, except voor mild side-effects from doxycycline, which will be negligible since the drug is administered in a subtherapeutical dose.

Contacts

Public
Medisch Centrum Alkmaar

Wilhelminalaan 12
1815JD
NL
Scientific
Medisch Centrum Alkmaar

Wilhelminalaan 12
1815JD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• GOLD II COPD (FEV1/FVC < 70%; 50% < FEV1 < 80% predicted).
• Stable disease (no exacerbations in the last 3 months).
• Age >40 yrs.
• Written informed consent.

Exclusion criteria

• Infections and/or use of antibiotics in the last month.
• Allergy for tetracyclines or a history of substantial side-effects.
• Active respiratory diseases other than COPD (e.g. sarcoidosis, tuberculosis, lung cancer, bronchiectasis).
• Signs and/or symptoms consistent with an acute exacerbation of COPD (AECOPD), such as increase in dyspnea, increase in sputum volume or change of sputum color from mucoid to purulent.
• Signs and/or symptoms of a current respiratory or non-respiratory infection.
• Use of oral or intravenous corticosteroids or other immunosuppressive drugs within the last month.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2008
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	doxycycline
Generic name:	doxycycline
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	15-04-2008
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	EUCTR2007-004262-41-NL
CCMO	NL19032.094.08