

# The effect of azithromycin in patients with COPD and chronic productive cough.

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To determin the effect of low dose azithromycin ( 3 times a week 250 mg) on the cough related health status in patients with COPD and chronic productive cough.In a randomized controlled study.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Bronchial disorders (excl neoplasms)
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON31487

### Source

ToetsingOnline

### Brief title

CACTUS

### Condition

- Bronchial disorders (excl neoplasms)

### Synonym

chronic bronchitis and emphysema., COPD

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Isala Klinieken

**Source(s) of monetary or material Support:** maatschap longziekten

## Intervention

**Keyword:** Azithromycin, COPD, LCQ, productive coughing

## Outcome measures

### Primary outcome

LCQ (leicester cough questionnaire)

### Secondary outcome

Short form 36, SGRQ.

FEV1, VC (spirometry), inflammatory markers sputum, microbiology sputum.

## Study description

### Background summary

In patients with COPD, chronic productive cough is a major symptom that can be resistant to the usual medication and smoking cessation. The productive coughing certainly has an influence on the quality of life, but possibly also contributes to a worse outcome by an ongoing inflammatory proces. In our hospital patient with chronic productive coughing are sometimes prescribed Azithromycin in a low dose, with surprisingly good effect . In other inflammatory pulmonal diseases like CF, diffuse panbronchiolitis and bronchiectasis the effect of Azithromycin on the inflammatory effect has allready been investigated and confirmed.

There is no randomized controlled study on the effect on COPD.

### Study objective

To determin the effect of low dose azithromycin ( 3 times a week 250 mg) on the cough related health status in patients with COPD and chronic productive cough. In a randomized controlled study.

### Study design

At least 84 pat. with COPD gold 2-4 in our outpatient clinic with chronic productive cough ( more than 3 months a year , two subsequent years) will be randomized, double blind to a therapy low dose azithromycin or placebo for 12 weeks.

The effect of this therapy will be measured by questionnaires on cough-related

quality of life, the LCQ (leicester cough questionnaire), short form 36 and the SGRQ (st George questionnaire) will be used.  
A spirometry will be done before and after 12 weeks and a sputum analyses on inflammatory markers and bacteria.

### **Study burden and risks**

The risk of participation is low. Azithromycin is a frequently used antibiotic without SUSAR's (except for infrequent allergic reactions) and is given here in a low dose.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

1. Patients > 40 years old, in our outpatient clinic with chronic cough and COPD (gold 2-4).
2. Chronic cough is defined as a cough > 12 weeks duration, 2 years in a row.
3. Analysed for bronchiectasis prior to participation.

## Exclusion criteria

1. Use of i.v. or oral corticosteroids and or antibiotics for an exacerbation 3 weeks before inclusion
2. Patients suffering from other relevant lung diseases.
3. Clinically relevant abnormal laboratory values suggesting an unknown disease requiring further clinical evaluation.
4. Liver disease, (ALAT and/or ASAT levels two or more times the upper limit of normal).
5. Pregnancy or lactation.
6. Use of macrolides the last 6 weeks prior to inclusion.
7. Allergy or intolerance to macrolides.
8. Other research medication started 2 months prior to inclusion.

## Study design

### Design

Study phase:	3
Study type:	Observational non invasive
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):	01-03-2008
Enrollment:	84
Type:	Anticipated

## Medical products/devices used

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

## Ethics review

Approved WMO	
Date:	16-09-2008
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO	
Date:	25-09-2008
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO	
Date:	16-07-2009
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

## 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**

EudraCT

CCMO

**ID**

EUCTR2008-000800-96-NL

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