Safety and Tolerability of Nebulized Amoxicillin-Clavulanic Acid in Patients with COPD.

No registrations found.

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

Summary

ID

NL-OMON26217

Source
Nationaal Trial Register

Brief title
STONAC

Health condition

COPD

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
P.O.Box 50.000
7500 KA Enschede
The Netherlands
Source(s) of monetary or material Support: initiator:
Onderzoeksbureau longgeneeskunde
Medisch Spectrum Twente
P.O.Box 50.000
7500 KA Enschede
The Netherlands

Intervention

Outcome measures

Primary outcome

To investigate the safety and tolerability of inhalation of nebulized amoxicillin clavulanic acid, as determined by spirometry and adverse effects monitoring.

Secondary outcome

To investigate dose exposure data as determined by sputum and serum concentrations of amoxicillin.

Study description

Background summary

N/A

Study objective

Not applicable: Phase 1 study --> Safety and Tolerability of Nebulized Amoxicillin-Clavulanic Acid in Patients with COPD.

Study design

A 3 hour follow up will take place. After 3 hours a blood sample will be obtained and coughed up sputum is collected throughout the 3 hours.

Intervention

The included patients will be given amoxicillin clavulanic acid by inhalation in four dosing steps.

Contacts

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Eligibility criteria

Inclusion criteria

1. A clinical diagnosis of stable COPD, as defined by GOLD criteria;

2. Able to produce sputum;

3. Age 40 years or over;

4. Current or former smoker.

Exclusion criteria

1. Exacerbation or use of prednisolone or antibiotics 4 weeks related to an exacerbation prior to enrolment;

2. Current pneumonia, defined as an acute respiratory tract illness associated with radiographic shadowing on a chest radiograph which was neither pre-existing nor of any other cause;

3. Allergy for penicillin, amoxicillin or clavulanic acid;

4. Respiratory insufficiency and hypercapnia measured by arterial blood gas analyses;

5. FEV1 postbronchodilator < 1.2 l.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-10-2011
Enrollment:	8
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-09-2011
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	NL2943
NTR-old	NTR3090
Other	ABR : 37727
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A