Safety and Tolerability of Nebulized Amoxicillin-Clavulanic Acid in Acute Exacerbations of COPD.

No registrations found.

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

Summary

ID

NL-OMON21366

Source
NTR

Brief title
STONAC 2

Health condition

Acute exacerbation of COPD

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Medisch Spectrum Twente

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Amoxicillin levels in sputum give information about the appropriateness of the given dose.

Study description

Background summary

N/A

Study objective

Not applicable: Phase II study --> Safety and Tolerability of Nebulized Amoxicillin-Clavulanic Acid in Acute Exacerbations of COPD.

Study design

Nebulizations will take place during hospitalization with a maximum of 7 days. Nebulization will take place two times a day. After every nebulization the patient will fill in a short questionnaire. Before and after the first nebulization spirometry will take place. Sputum will be collected before the second inhalation, at three times at day three and before the last inhalation. A blood sample will be taken at day 3.

Intervention

The included patient will be given amoxicillin clavulanic acid by inhalation twice daily in a fixed dose.

Contacts

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Eligibility criteria

Inclusion criteria

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

2. Hospitalized for an acute exacerbation of COPD;

3. Admitted to ward A4 or C4;

4. Able to produce sputum;

5. Age 40 years or over;

6. Current or former smoker.

Exclusion criteria

1. Current pneumonia, defined as an acute respiratory tract illness associated with radiographic shadowing on a X-ray or CT-scan of the chest which was neither pre-existing nor of any other cause;

2. Allergy for penicillin, amoxicillin or clavulanic acid. (patients must have been treated with amoxicillin before without a report of allergic reactions);

3. History of severe AECOPD requiring mechanical ventilation;

4. Recently diagnosed or unresolved lung malignancy;

5. Impaired renal function (Creatinine Clearance < 20 ml/min);

6. Congestive Heart Failure (NYHA III-IV).

During the trial the patient cannot be treated with systemic amoxicillin clavulanic acid.

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:	Pending
Start date (anticipated):	01-05-2013
Enrollment:	8
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-05-2013
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	NL3817
NTR-old	NTR3983
CCMO	NL44131.044.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A