Amoxicillin-clavulanic acid Levels in Sputum After Nebulization

No registrations found.

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

Summary

ID

NL-OMON28084

Source
NTR

Brief title
ALSAN

Health condition

AECOPD (Acute exacerbation of COPD)
inhalation
nebulization
antibiotics
amoxicillin

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Dose exposure data as determined by sputum concentrations of amoxicillin. Amoxicillin

levels in sputum give information on the appropriateness of the dose given from a calculated time > MIC.

Secondary outcome

The safety and tolerability of inhalation of nebulized amoxicillin clavulanic acid by adverse effects monitoring.

Study description

Background summary

N/A

Study objective

Not applicable: kinetic study to investigate sputum amoxicillin levels (time > MIC) during 3 consecutive days of inhaling amoxicillin clavulanic acid b.i.d.

Study design

Nebulizations will take place for 3 days while hospitalized. Nebulization will take place two times a day. Every day the patient will fill in a short questionnaire evaluating the tolerability of the nebulization. To obtain top, mid and trough sputum levels of amoxicillin between two doses, patients are asked to give up sputum after inhalation(top), at one point during the day(mid) and before the next inhalation (trough).

Intervention

The included patient will be given amoxicillin clavulanic acid by inhalation twice daily in a fixed dose. (for 3 days)

Contacts

Public
Medisch Spectrum Twente Hospital
Department of Pulmonology
PO Box 50.000
P.D.L.P.M. Valk, van der
Enschede 7500 KA
The Netherlands

+31 (0)53 4872610
Scientific
Medisch Spectrum Twente Hospital
Department of Pulmonology
PO Box 50.000
P.D.L.P.M. Valk, van der
Enschede 7500 KA
The Netherlands
+31 (0)53 4872610

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 the ward of pulmonary medicine

4) Age 40 years or over

5) 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.

3) Recently diagnosed or unresolved lung malignancy

4) amoxicillin or clavulanic acid therapy within 3 days prior to admission

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2016
Enrollment:	21
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-05-2016
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	NL5712
NTR-old	NTR5865
Other	: ABR55935

Study results

Summary results
N/A