Nebulising Amoxicillin-Clavulanic Acid in Patients with COPD (NACAP)

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To investigate whether inhalation of nebulised amoxicillin clavulanic acid is effective in reaching amoxicillin sputum levels >= MIC 90 in patient with an exacerbation of COPD.

Ethical review	Not approved
Status	Will not start
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON36305

Source
ToetsingOnline

Brief title
NACAP

Condition

- Respiratory tract infections

Synonym
COPD

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Ministerie van OC&W,Romedic levering vernevelapparatuur

Intervention

Keyword: amoxicillin, clavulanic acid, COPD, inhalation, nebulizers and vaporizers

Outcome measures

Primary outcome

Primary: At day 3 sputum samples will be collected and the amoxicillin concentration will be determined in order to obtain a number (percentage) of patients that adhere to an amoxicillin sputum level higher than the MIC90.

Secondary outcome

Secondary:

• To investigate whether nebulisation of amoxicillin clavulanic acid results in a decrease of hospitalisation days of patients with an exacerbation of COPD compared to the ASPECT study.

• To investigate the tolerability of nebulised amoxicillin clavulanic acid.

• To obtain information on distribution and systemic exposure of amoxicillin when nebulised.

Study description

Background summary

Previous research has shown that an amoxicillin concentration higher than the Minimal Inhibiting Concentration of 90% (MIC90) reduced the mean length of hospitalisation during a COPD exacerbation from 11 to 7 days. Furthermore most patients did not reach amoxicillin levels equal or higher than the Minimal Inhibiting Concentration of 90% (MIC90) when amoxicillin clavulanic acid was administered orally or intravenously. We think that more patients will achieve an adequate amoxicillin level in sputum when amoxicillin clavulanic acid is administered locally instead of systemic. Therefore in this study we want to apply nebulised amoxicillin clavulanic acid by inhalation.

Study objective

To investigate whether inhalation of nebulised amoxicillin clavulanic acid is effective in reaching amoxicillin sputum levels >= MIC 90 in patient with an exacerbation of COPD.

Study design

The study is designed as a single-arm prospective intervention study

Intervention

Patients that are considered for treatment with amoxicillin clavulanic acid will receive treatment by inhalation of 25/5 mg nebulised amoxicillin clavulanic acid twice daily instead of oral or intravenously administered amoxicillin. Further treatment will be according to common daily practice

Study burden and risks

Risk: Aerosolized delivery of antimicrobial agents is an attractive option for management of pulmonary infections, as this is an ideal method of providing high local drug concentrations while minimizing systemic exposure. Inhalation of nebulised amoxicillin clavulanic acid has not been described in literature. There are only two studies on tolerability of inhalation of amoxicillin. In these studies amoxicillin was well tolerated. However their sample sizes were small. There are no signs to suspect tolerability issues no more then there are with systemic administration. Local adverse effects such as cough, wheezing, shortness of breath, and respiratory irritation can occur with aerosolized delivery of antimicrobials. Therefore security measures will be taken. Benefit: This treatment has the potential of achieving better results, i.e. shortening of exacerbation than oral or intravenous administration. When the hypothesis is correct that failure of treatment by oral or intravenous intake results is related to low sputum levels then this new way of local administration could be off a substantial benefit in the treatment of exacerbations of COPD.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• A clinical diagnosis of COPD, as defined by GOLD criteria,
• Admitted with signs and symptoms of an exacerbation of COPD, defined as an acute negative change from the baseline, reported by the patient, in dyspnoea and/or sputum volume and/or colour of sputum (yellowish or greenish sputum) and/or cough
• Age 40 years or over
• Current or former smoker.

Exclusion criteria

• Impaired renal function (GFR < 30)
• 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.
• Allergy for penicillin, amoxicillin or clavulanic acid
• Respiratory insuffiency and hypercapnia measured by arterial blood gas analyses

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-10-2011
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	amoxicillin
Generic name:	amoxicillin
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	clavulanic acid
Generic name:	clavulanic acid
Registration:	Yes - NL outside intended use

Ethics review

Not approved

Date:	15-06-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	EUCTR2011-001972-20-NL
CCMO	NL35340.044.11
Other	NTR nummer volgt