# Nebulising Amoxicillin-Clavulanic Acid in Patients with COPD.

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Nebulizing amoxicillin clavulanic acid is more effective for reaching amoxicillin levels in sputum > MIC90 than amoxicillin clavulanic acid given by oral or intravenous administration.

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving tijdelijk gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON22557

**Bron**
Nationaal Trial Register

**Verkorte titel**
NACAP

**Aandoening**

COPD
exacerbation
nebulization
inhalation
amoxicillin

### Ondersteuning

**Primaire sponsor:** Dr. P.D.L.P.M. van der Valk
**Overige ondersteuning:** N/A

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Sputum concentration of amoxicillin at day 3.

# Toelichting onderzoek

**Achtergrond van het onderzoek**

Rationale:

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.

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.

Secondary Objective(s):

To investigate whether sputum levels ≥ MIC 90 due to nebulisation of amoxicillin clavulanic acid result in a decreased hospital stay during exacerbations of COPD compared to sputum levels

Study design:

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

Study population:

Patients hospitalised for an exacerbation in COPD at the inpatient pulmonary department of Medisch Spectrum Twente in Enschede, the Netherlands, will be recruited.

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.

Main study parameters/endpoints:

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: the duration of hospital stay will be recorded.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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.

## Doel van het onderzoek

Nebulizing amoxicillin clavulanic acid is more effective for reaching amoxicillin levels in sputum > MIC90 than amoxicillin clavulanic acid given by oral or intravenous administration.

## Onderzoeksopzet

N/A

**Onderzoeksproduct en/of interventie**

Nebulization of amoxicilline clavulanic acid. They 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.

# Contactpersonen

## Publiek

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Department of Pulmonology<br>
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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

2. 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;

3. Age 40 years or over;

4. Current or former smoker.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Current treatment with amoxicillin or amoxicillin clavulanic acid;

2. Impaired renal function (GFR < 30);

3. 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;

4. Allergy for penicillin, amoxicillin or clavulanic acid;

5. Respiratory insuffiency and hypercapnia measured by arterial blood gas analyses.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving tijdelijk gestopt |
| (Verwachte) startdatum: | 01-10-2011 |
| Aantal proefpersonen: | 30 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL2770 |
| NTR-old | NTR2910 |
| Ander register | : |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A