

Is antibiotic treatment associated with reduced risk of a subsequent exacerbation and mortality in chronic obstructive lung disease? A randomized clinical trial.

Gepubliceerd: 09-09-2010 Laatste bijgewerkt: 18-08-2022

We postulate that antibiotics added to corticosteroids in the treatment of exacerbations of COPD, will prolong time to next exacerbation.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28324

Bron

Nationaal Trial Register

Verkorte titel

TEXACOLD trial

Aandoening

COPD, antibiotics, exacerbation, doxycyclin

COPD, antibiotica, exacerbatie, doxycycline

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam

Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Time to next exacerbation.

Toelichting onderzoek

Achtergrond van het onderzoek

Chronic obstructive pulmonary disease (COPD) is a very prevalent, chronic disease. For the majority of COPD outpatients, it is at the present not clear whether during an exacerbation antibiotics should be added to treatment with corticosteroids. On the short term, antibiotic treatment has limited added value. However, retrospective data manifest a prolonged time to the next exacerbation. The major drawback of treating all exacerbations with antibiotic, will be the significant increase in overall antibiotic consumption, which will fuel the increasing rates of resistance among respiratory pathogens. Therefore, benefits of antibiotic treatment have to be confirmed in a prospective study.

Doel van het onderzoek

We postulate that antibiotics added to corticosteroids in the treatment of exacerbations of COPD, will prolong time to next exacerbation.

Onderzoeksopzet

1. At inclusion in cohort: History, clinical evaluation, sputum culture;

2. At inclusion in randomized clinical trial: History, clinical evaluation, sputum culture;
3. Follow up at week 1, 2, 3, 4, 12, 24, 36, 48, 60, 72, 84, 96 after inclusion in randomized clinical trial.

Onderzoeksproduct en/of interventie

A cohort of 1000 participants will be collected. In case of an exacerbation, patients will be randomized between doxycyclin and placebo. Not eligible for randomization are patients who should be treated with antibiotics according to current guidelines, patients who require hospitalization, patients who currently use antibiotics and patients who used antibiotics for a respiratory tract infection in the last 3 weeks.

Target number of participants in the RCT is 470 (needed to collect 251 second exacerbations).

Contactpersonen

Publiek

P.O. Box 22660
P. Velzen, van
AMC, Department of Infectious Diseases, F5-260
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5664359

Wetenschappelijk

P.O. Box 22660
P. Velzen, van
AMC, Department of Infectious Diseases, F5-260
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5664359

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 45 years and older;
2. COPD GOLD 1, 2 or 3;
3. At least 1 documented or self-reported exacerbation during the past 3 years;
4. Last exacerbation at least 4 weeks prior to inclusion, and symptoms returned to patient's baseline level;
5. A smoking history of at least 10 pack years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Poor cognitive functioning;
2. Poor mastering of the Dutch language;
3. Allergy for doxycyclin;
4. Pregnancy;
5. A life expectancy less than 1 month.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2010

Aantal proefpersonen: 470
Type: Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 09-09-2010
Soort: Eerste indiening

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	NL2392
NTR-old	NTR2499
Ander register	METC AMC : 10/057
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A