CRP-guided antibiotic treatment in patients hospitalized with acute exacerbation of COPD patients. The CATCH (CRP guided Antibiotic Treatment in COPD exacerbations admitted at the Hospital) study.

Published: 23-05-2011
Last updated: 04-05-2024

OBJECTIVESIn this study CRP-guided antibiotic therapy will be compared with GOLD antibiotic therapy in AECOPD with special attention at consumption antibiotics and treatment failure.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON39092

Source
ToetsingOnline

Brief title
CRP-guided therapy in AECOPD (Acute Exacerbation of COPD)

Condition

- Bacterial infectious disorders
- Respiratory tract infections

Synonym
bronchitis, lower respiratory tract infection

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: subsidie Foreest Medical School

Intervention

Keyword: Acute exacerbation, Antibiotic treatment, COPD, C-reactive protein

Outcome measures

Primary outcome

Main study parameter/endpoint

Reduction in antibiotic treatment prescribed in the CRP guided therapy during the period of 30 days after entering the study. Incidence of pulmoanary infiltrates on CT scan in patients with AECOPD.

Secondary outcome

1. The effect of treatment will be estimated by comparing the percentage of treatment failure at day 30.

2. Time to next exacerbation reported at 3, 6, and 12 months follow-up.

3. Length of hospital stay.

4. Symptom scores (VAS-LRTI) on admission, day 14, at day 30.

5. Quality of life (Clinical COPD Questionnaire) on admission, 30 days.

6. Adverse effects of treatment (days 1-10 and day 30).

7. The relation between biomarkers (CRP,PCT) and pulmonary infiltrates observed on CT-scan.

Study description

Background summary

SUMMARY

Rationale: Acute exacerbations are key events in chronic obstructive pulmonary disease (COPD), resulting in poorer quality of life. Causes include irritants, viruses and bacterial pathogens. These exacerbations are often treated with a combination of corticosteroids, bronchodilators and antibiotics, but the benefit of antibiotic therapy remains controversial. Several trials studying antibiotic treatment in AECOPD showed conflicting data, with several large studies failing to demonstrate superiority of antibiotic therapy over placebo. Other trials indicated that antibiotic therapy is effective in patients who have at least two of the following symptoms: increased dyspnoea, increased sputum volume and increased sputum purulence. Sputum purulence is most discriminating variable for the prescription of antibiotic treatment. However, the color of sputum reported by patients is not always reliable. In previous study we have demonstrated that CRP may more accurate predict who may benefit from antibiotic
therapy or not.
Objective: CRP-guided antibiotic therapy will be compared with antibiotic therapy according to the GOLD strategy in AECOPD. Our aim is that CRP guided therapy will lead to 20% reduction in antibiotic consumption at day 10.
Study design: randomized controlled intervention trial
Study population: Hospitalised COPD patients with acute exacerbation.
Intervention (if applicable): Patients with AECOPD will be assigned to either CRP guided therapy or antibiotic therapy according to the GOLD strategy, that means two of three symptoms should be present: increased dyspnoe and/or increased sputumproduction and at least change of sputum color.
Main study parameters/endpoints: The main endpoint of the study is the reduction in antibiotic consumption at day 10. Furthermore, the real incidence of infiltrates in AECOPD will be studied. As secondary outcome the objectives length of hospitalization, time to treatment failure within 30-days and time to next exacerbation will be assessed. Subjective improvement in quality of life will be measured by symptoms (VAS-LRTI) and disease-specific (Clinical COPD Questionnaire[CCQ]) quality of life instruments. Finally, adverse effects of the antibiotic treatment will be recorded.The relation between the level of biomarkers the presence of infiltrates on the low dose CT will be compared .
In order to observe a significant difference of antibiotic consumption, 60% in standard antibiotic group and 40% in CRP guided antibiotic group, with a power of 0.8, a total of 220 women have to be assigned by randomisation to each group.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients in both treatment arms will receive a non-experimental treatment. Both treatment options are recognized as part of standard care. The burden associated with participation is limited to a total

of 3 visits to the hospital and phone call for data assessment at regular follow-up. There are no specific risks involved in participating.

Study objective

OBJECTIVES

In this study CRP-guided antibiotic therapy will be compared with GOLD antibiotic therapy in AECOPD with special attention at consumption antibiotics and treatment failure.

Study design

STUDY DESIGN

The present study will be prospectively performed using the following study design: A randomized controlled intervention trial. Patients admitted at the Medical Centre Alkmaar or Medical Spectrum Twente with an acute exacerbation of COPD are asked to participate the study. After informed consent patients will be randomized in 2 groups, namely CRP-guided (cut-off 50 mg/L) antibiotic therapy (group 1) versus GOLD antibiotic therapy (group 2). Patients with CRP >= 50 mg/L receive antibiotic treatment, whereas in patients with CRP< 50 mg/L antibiotic treatment will be withheld. All patients randomized in group 2 receive antibiotic treatment if two of three symptoms such as increased dyspnoe and/or increased sputumproduction and at least change of sputum color are present. The type antibiotic treatment is standardized. All other co-medication for ACEOPD in both groups are also standardized (corticosteroids and bronchodilators). All other treatment (oxygen, physiotherapy,etc.) will be standardized as accurate as possible. We expect that CRP-guided therapy will be as good as standard antibiotic treatment, that means that patients with CRP < 50 mg/L can be safely treated without antibiotic treatment.

Intervention

Study procedures
Patients admitted at the hospital with an AECOPD will be asked to participate by residents and pulmonologists. After checking the inclusion and exclusion criteria a patient/ relative is asked to participate. The patient/relative will receive written and verbal information about the study. If the patient/relative wants to cooperate he or she is asked to sign the informed consent. Subsequently, the patient will be randomized in of the two groups. Routine diagnostic tests, such as laboratory examination, ECG, chest X-ray, and arterial blood gas analysis will be performed at admission. Treatment is initiated immediately, including antibiotic treatment accept in those patients

with CRP < 50 mg/L where antibiotic treatment is withheld (group 1). Patients of group 2 are not treated with antibiotics if they do not fulfill the critera for bacterial infection. If possible. sputum will be obtained before antibiotic treatment is started. When a patient is substantially improved, he or she will discharged from the hospital. Outpatient visits are scheduled at 30 days, 3 months, 6 months and 12 months(by phone) follow-up.

Study burden and risks

We expect that patients with bacterial AECOPD can be treated more efficiently. Our aim is, that viral infection or a low grade bacterial infection is associated with a low level of CRP. These AECOPD do respond better on treatment with corticosteroids than antibiotic treatment. Moreover, antibiotic treatment may induce adverse effects, such gastro intestinal disturbances and allergic reactions. By systematically prescribing antibiotic drugs in patients with AECOPD, antibiotic pressure in the hospital is increasing and has a negative effect on the development of resistant bacteria.
All patients will be carefully monitored, and therefore the risk withholding an antibiotic in episode of worsening AECOPD is negligible. The non-intervention group will be treated as usual.

Contacts

Public
Medisch Centrum Alkmaar

Wilhelminalaan 12
Alkmaar 1815JD
NL
Scientific
Medisch Centrum Alkmaar

Wilhelminalaan 12
Alkmaar 1815JD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion criteria:
• Age 40 or over. No upper age limit will be employed.
• Written informed consent obtained.
• Change in the patient*s baseline dyspnoea, cough, and/or sputum that is beyond normal day-to-day variations, is acute in onset, and may warrant a change in regular medication in a patient with underlying COPD.
• Patients have to be capable of ingesting oral medication.
• Patients have to mentally capable of participating in the study (able to complete questionnaires and perform lung function tests).
• Life expectancy >= 30 days.
• Smoking history > 10 packyears

Exclusion criteria

Exclusion criteria
• Pregnant or lactating women
• Pretreatment with corticosteroids (cumulative dosis >210 mg) for the present exacerbation.
• Progression or new radiographic abnormalities on the chest X-ray.
• Bronchiectasis (HRCT confirmed).
• Cystic fibrosis
• Tuberculosis
• Immunodeficiency disorders such as AIDS, humoral immune deficiency, ciliary dysfunction etc., and the use of immunosuppressive drugs (>30 mg prednisolone maintenance dose or equivalent for more than 4 weeks).
• Recent or unresolved lung malignancy.
• Other disease likely to require antibiotic therapy, such as recurrent sinusitis or urinary tract infection.
• Significant gastrointestinal or other conditions that may affect study drug absorption.
• Class III or IV congestive heart failure or stroke.
• Newly diagnosed pulmonary embolism
• Chonic incresead CRP of any cause (history, lab exam)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-07-2011
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO Date:	23-05-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-02-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-08-2012
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-04-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-11-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-03-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT01232140
CCMO	NL33284.094.10