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The effects of the use of antibiotics during acute exacerbations in chronic obstructive pulmonary disease (COPD) on the severity and duration of exacerbations: the ABC-trial

Submission date 19/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/12/2005	**Overall study status** Completed	
Last Edited 11/07/2019	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR351; MEC: P04-08

Study information

Scientific Title

The effects of the use of antibiotics during acute exacerbations in chronic obstructive pulmonary disease (COPD) on the severity and duration of exacerbations: the ABC-trial

Acronym
ABC-trial

Study objectives
Primary:
Additional treatment with antibiotics in case of an exacerbation of chronic obstructive pulmonary disease (COPD) will not lead to a reduction in the severity and duration of exacerbations compared to treatment without antibiotics.

Secondary:
The relapse rate (defined as a new exacerbations within 28 days) is not reduced in case of additional treatment with antibiotics of a COPD exacerbation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Double blinded, randomised, placebo controlled, parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
Intervention group: Prednisolone 30 mg for 7 days, antibiotics (Amoxicillin/clavulanic acid three times daily for 7 days) and a Body Area Network for monitoring of health status.
Control group: Prednisolone 30 mg for 7 days, placebo of Amoxicillin/clavulanic acid (three times daily for 7 days) and a Body Area Network for monitoring of health status.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Prednisolone, antibiotics (amoxicillin/clavulanic acid)

Primary outcome(s)

Duration of the exacerbations. This is measured by a Body Area Network, a symptom diary and lung function (FEV1 and PEF).

Key secondary outcome(s))
1. Severity of the exacerbations. This is measured by a Body Area Network, a symptom diary and lung function (FEV1 and PEF).
2. Relapse rate. A relapse is defined as an exacerbation that resolves due to the blinded treatment but re-occurs within 28 days of the treated exacerbation.
3. Cost-effectiveness of treatment with antibiotics
4. Use of rescue-medication, recorded in the symptom diary
5. Quality of life, measured by the Chronic Respiratory Questionnaire and the COPD Chronic Questionnaire

Completion date
01/01/2007

Eligibility

Key inclusion criteria
1. Patients of the outpatient clinic of the Medical Spectrum Twente
2. Aged between 40 and 75 years
3. A clinical diagnosis of COPD as defined by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria
4. A signed and dated written informed consent from the subject prior to study participation
5. Patients with COPD presenting one or two of the following characteristics:
5.1. A positive Grams stain of the sputum
5.2. A clinically relevant decrease of lung function, defined as a decrease in forced expiratory volume in one second (FEV1) of 200 ml or more and 12% or more from baseline value
5.3. Two or more exacerbations in the previous year
6. Present with signs and symptoms of an exacerbation at the outpatient clinic
7. Current smoker or ex-smoker
8. Able to understand, read and write Dutch

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
35

Key exclusion criteria

1. Serious other disease with a low survival rate
2. Clinical symptoms (e.g. temperature greater than 38.5°C), indicating pneumonia and a thorax X-ray positive for pneumonia
3. Another disease, which influences bronchial symptoms and/or lung function (e.g. cardiac insufficiency, sarcoidosis, pulmonary embolism, rib fracture, pneumonia and bronchial carcinoma)
4. Severe psychiatric illness
5. Uncontrolled diabetes mellitus
6. Need for regular oxygen therapy
7. Maintenance therapy with antibiotics
8. Subject with a known hypersensitivity to amoxicillin/clavulanic acid (Augmentin®)
9. Use of antibiotic 4 weeks before study entry
10. Use of prednisolone (except for a maintenance ration) 4 weeks before study entry
11. An exacerbation less than 4 weeks before study entry
12. Alpha1-antitrypsine deficiency
13. Former participation in the ABC-trial

Date of first enrolment
25/05/2005

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Medisch Spectrum Twente
Enschede
Netherlands
7500 KA

Sponsor information

Organisation
Medisch Spectrum Twente (Netherlands)

ROR
https://ror.org/033xvax87

Funder(s)

Funder type
Government

Funder Name
SENTER - A branch of the Dutch Ministry of Economic Affairs (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/12/2014	11/07/2019	Yes	No