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# Treatment of exacerbations of Chronic Obstructive Pulmonary Disease - a co-operation between primary health care and hospital care: a prospective, randomised trial

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| **Submission date**<br>12/09/2005 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>12/09/2005 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>12/04/2021 | **Condition category**<br>Respiratory | [_] Individual participant data<br>[_] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

**Study website**
http://www.picassovoorcopd.nl

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

### Scientific Title
Treatment of exacerbations of Chronic Obstructive Pulmonary Disease - a co-operation between primary health care and hospital care: a prospective, randomised trial

### Acronym
PICASSO (Partners in Care Solutions) for COPD

### Study objectives
Will adequate treatment in primary care, supported by a structured co-operation with the hospital, lead to improvement in patients' health (faster recovery) and the health care process (use of antibiotics and health care services)?

### Ethics approval required
Old ethics approval format

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

### Study design
Randomised, active controlled, parallel group, multicentre trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Chronic Obstructive Pulmonary Disease (COPD)

### Interventions
Control arm: patients with exacerbation COPD receive 'care as usual'.
Intervention arm: patients with exacerbations are treated by their General Practitioner (GP)

following the study protocol. This means a short course of oral steroids (30 mg daily, seven to ten days, in accordance with the Dutch College of General Practitioners [NHG] guideline for COPD). Antibiotics should be prescribed following the NHG guideline for COPD. There is an extra opportunity to refer to a pulmonologist for a one-time consultation.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Improvement in patients' health (faster recovery).

### Secondary outcome measures
The health care process (use of antibiotics and health care services).

### Overall study start date
01/11/2004

### Completion date
01/05/2006

## Eligibility

### Key inclusion criteria
1. Patient meets the clinical criteria of Chronic Obstructive Pulmonary Disease (COPD):
a. Chronic bronchitis: chronic cough and sputum production on most days during at least three months of the year, during at least two consecutive years and/or
b. COPD defined as an expiratory flow obstruction determined by spirometry, where the disorder does not vary seriously during several months of observation
2. Diagnosis of COPD in medical dossier
3. Indications for exacerbation
a. Increased dyspnoe, +/- accompanied by increased volume and/or purulence of sputum and/or cough
b. Increased dyspnoe developed in a short period (less than four weeks)
c. Adaptation in medication is necessary

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
128

### Key exclusion criteria
1. Inadequate cognitive functioning
2. Inadequate of mastering the Dutch language
3. Terminal patient
4. Other infection at the same time that needs antibiotic treatment
5. Serious underlying diseases: Acquired Immune Deficiency Syndrome (AIDS), neutropenia less than 1.0 x 10^9/l
6. Age less than 40 or more than 80 years

### Date of first enrolment
01/11/2004

### Date of final enrolment
01/05/2006

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**Academic Medical Center (AMC)**
Amsterdam
Netherlands
1105 AZ

## Sponsor information

### Organisation
University Maastricht (The Netherlands)

### Sponsor details
CAPHRI Research Institute
P.O. Box 616
Maastricht
Netherlands
6200 MD

### Sponsor type
University/education

### ROR
https://ror.org/02jz4aj89

# Funder(s)

**Funder type**
Industry

**Funder Name**
Pfizer (The Netherlands)

**Alternative Name(s)**
Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen

**Funding Body Type**
Government organisation

**Funding Body Subtype**
For-profit companies (industry)

**Location**
United States of America

**Funder Name**
Boehringer Ingelheim (The Netherlands)

**Alternative Name(s)**
Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim International GmbH, BI, BIPI

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
For-profit companies (industry)

**Location**
United States of America

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

2008 results published in thesis https://pure.uva.nl/ws/files/1587855/59316_thesis.pdf (added 12/04/2021)

**Intention to publish date**

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration