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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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# Additional identifiers

**Protocol serial number** 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

#### Study type(s)

Treatment

#### 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(s)

Improvement in patients' health (faster recovery).

# Key secondary outcome(s))

The health care process (use of antibiotics and health care services).

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

Αll

#### 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  $1.0 \times 10^9/l$
- 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)

#### **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, Pfizer Inc

## **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**

Individual participant data (IPD) sharing plan

IPD sharing plan summary

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes