

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

Submission date 12/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 12/04/2021	Condition category Respiratory	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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Contact details

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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

All

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