ISRCTN43868741 https://doi.org/10.1186/ISRCTN43868741

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	[_] Prospectively registered [_] Protocol
Registration date 12/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 12/04/2021	**Condition category** Respiratory	[_] Individual participant data [_] 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