

Immediate in-hospital reactivation of patients with an exacerbation of Chronic Obstructive Pulmonary Disease (COPD): Pulmofit-MST

Submission date 13/11/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 07/01/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/01/2008	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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NT1101

Study information

Scientific Title

Acronym

PULMOFIT-MST

Study objectives

Chronic Obstructive Pulmonary Disease (COPD) is a major cause of disability and mortality worldwide. Morbidity and mortality among COPD-patients are strongly related to acute exacerbations of COPD, which can be defined as sustained worsening of the patients condition, from stable state and beyond normal day-to-day variations, that is acute in onset and may warrant additional treatment in a patient with underlying COPD. Severe exacerbations may lead to hospital admissions and have a major impact on disease evolution and costs.

PulmoFit-MST, an immediate reactivation programme, will induce a reduction of the length of stay in the hospital, by preventing loss of peripheral muscle force and exercise capacity and thereby initiating a faster recovery of activities of daily living.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee (Medisch Etische Toetsingscommissie Medisch Spectrum Twente) on the 16th January 2006 (ref: P06-05).

Study design

Randomised, active controlled, parallel group, two armed trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Chronic Obstructive Pulmonary Disease (COPD)

Interventions

The protocol of the programme aimed at an active role of COPD-patients during their stay in the hospital. Patients in the intervention group were asked to perform three daily training sessions

of 15 minutes each. One daily session was assisted by a physiotherapist, while the other two had to be performed by the patients themselves.

PULMOFIT-MST consists of four levels of increasing difficulty. Within four hours after admission, level I was started by the nurse who distributed the workbook with the description of all exercises and who instructed the first exercises to the patient. Within 24 hours after admission, the physiotherapist visited the patient and continued the programme by choosing the appropriate follow-up level and determining the intensity of the exercises. Every day the physiotherapist evaluated the exercises and the appropriateness of the training level and training intensity. A workbook functioned as a daily diary in which the intensities of training exercises were noted by the physiotherapist and daily experiences and improvements by the patient. All disciplines (chest physicians, nurses, and physiotherapists) stimulated patients to perform all three daily PULMOFIT-MST sessions.

Patients in the control group received usual care, meaning treatment the patients would have received prior to this study.

The duration of the treatment depends on the length of the hospitalisation. Patients of the intervention group are treated according to the PULMOFIT-MST protocol during the whole hospitalisation period.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Length of hospital stay, defined as number of days between day of admission and day of medical discharge. Day of medical discharge was distinguished from the actual day of discharge because some patients remain in hospital longer than medically necessary (e.g. patients could not yet be referred to a nursing home).

Secondary outcome measures

1. Walking distance (3 minutes walking test)
2. Dyspnoea (Borg scale)
3. Health status (Clinical COPD Questionnaire)
4. Activities of daily living (Barthel Index)
5. Readmissions due to a COPD-exacerbation (less than 28 days), measured at 28 days

Measurements take place at the day of admission, day 4 and the day of medical discharge.

Overall study start date

01/02/2006

Completion date

01/02/2007

Eligibility

Key inclusion criteria

1. A clinical diagnosis of COPD according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria
2. A clinical diagnosis of an exacerbation of COPD for which hospitalisation was required
3. (Ex-) smoker
4. Age above 40 years
5. A life expectancy of at least 3 months
6. Able to understand and read Dutch
7. An informed consent from the subject prior to participation

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

80

Key exclusion criteria

1. Pneumonia
2. Fever (greater than 38.5°C)
3. Severe confusion
4. Severe heart failure, New York Heart Association (NHYA) class III or IV
5. Relevant co-morbidity seriously influencing mobility

Date of first enrolment

01/02/2006

Date of final enrolment

01/02/2007

Locations**Countries of recruitment**

Netherlands

Study participating centre

Haaksbergerstraat 55

Enschede

Netherlands

7513 ER

Sponsor information

Organisation

Dutch Asthma Foundation (The Netherlands)

Sponsor details

Postbus 5
Leusden
Netherlands
3830 AA

Sponsor type

Charity

ROR

<https://ror.org/00ddgbf74>

Funder(s)**Funder type**

Charity

Funder Name

Dutch Asthma Foundation (The Netherlands)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration