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Efficacy of pulmonary rehabilitation in moderate Chronic Obstructive Pulmonary Disease (COPD) patients in primary health care and maintenance of benefits at 2 years

Submission date
14/01/2010

Recruitment status
No longer recruiting

Registration date
11/02/2010

Overall study status
Completed

Last Edited
14/02/2013

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Marató TV3 PI04/2610

Study information

Scientific Title
A 3-arm randomised controlled parallel group trial to determine the efficacy of pulmonary rehabilitation in moderate Chronic Obstructive Pulmonary Disease (COPD) patients in primary health care and maintenance of benefits at 2 years

Acronym
REHPOCAP

Study objectives
1. In patients with COPD, a long term (24 months) programme of pulmonary rehabilitation will improve the quality of life compared with patients that follow a short term duration (12 weeks) programme of pulmonary rehabilitation and compared with those who follow usual care
2. Patients included in the long term programme have less exacerbations for COPD, and a decreased number of hospital admission and inpatient stays in hospitals compared with patients with a short duration pulmonary rehabilitation programme and compared with those patients who follow usual care.
3. Patients involved in a short term pulmonary rehabilitation programme (12 weeks) improve the parameters mentioned above but the improvement is not maintained at 24 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The trial obtained approval from the Majorca Primary Care Research Committee and from the regional Ethical Committee of Clinical Research (ref: IB370/04 PI)

Study design
Randomised three arm blinded parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a pulmonary rehabilitation booklet or patient information sheet (in Spanish).

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

Interventions
Patients in the two intervention groups will receive a pulmonary rehabilitation programme of three, 90 minutes weekly sessions during 12 weeks. The sessions consist of four types of interventions:
1. Educative sessions on anatomy and physiology of respiratory system, correct use of inhalators and a brief counselling to stop smoking. This action will be carried out in weeks 1, 6 and 12.
2. Respiratory Physiotherapy (self conscious breathing control, diaphragmatic breathing control, chest wall exercises, and abdominal muscles wall work) during weeks 1, 6 and 12.
3. Low intensity peripheral muscle training. It consists on abdominal and upper and lower limbs exercises, shoulder and arms circling, raising weights and other exercises. The program has been described by (Clark CJ 1996) and has been used in other clinical trials (Normandin EA 2002, Foglio K 1999). Each exercise is repeated between 8-10 times during 45 minutes. It takes one and half hours to complete exercise with small breaks. The program has 12 weeks duration.
4. Patients will be asked to practice a low level home-based exercise program adapted to individual characteristics. Compliance with home-based programme will be assessed every two weeks with the patient and registered in a spread-sheet. Interventions will be carried out in groups of 8-10 persons. A primary care nurse will carry out the educative intervention and the exercises programme by two physiotherapists in two Primary Care Physiotherapy Units. Nurses will be trained in the educative intervention and group dynamic. In order to standarise physiotherapist intervention, a 7 days tuition programme will be developed.
5. After completing the 12 weeks pulmonary rehabilitation programme, each patient will be included in the activities of the initially assigned group RHBM, or RHB.
5.1. patients in group RHB will follow their usual care with his physician and nurse.
5.2. patients in group RHBM will follow a weekly session of maintenance till the end of the programme at 24 months.
5.3. patients in control group will follow their usual care with their physician and nurse from the inception.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Quality of life:
Assessed by the Spanish validated version of the Chronic Respiratory Questionnaire (CRQ) a 20 items scale, administered by an interviewer, designed for COPD patients. Each item is graded on 7-point likert scale. It includes four domains: dyspnoea (5 items), fatigue (4 items), emotional function (7 items) and mastery (4 items). It scores each dimension summing the punctuation of each item or through items average. The clinical repercussion of changes in the punctuation of CRQ after a therapeutic intervention (minimal important difference - MDCI) is 0.5 per item and 10 global scoring, a change of 2.5 in dyspnoea domain, 2 for fatigue and mastery and 3.5 for emotional function (Reardon J 1994). The questionnaire was adapted and validated by Güell et al (Güell R et al. Eur Respir J 1998; 11: 55-60.), showing good psychometric properties, high reliability and sensitivity to changes.

Secondary outcome measures
1. The 6-min-walking test:
Conducted along a flat corridor during 25 minutes. Each patient will be instructed and receive standarised encouragement to walk from one end to the other, covering as much ground as

possible during the allotted time, as recomended by the American Thoracic Society.
2. Patients will rate their level of dyspnoea in daily activities through the Dyspnoea Index (Borg scale):
A 10cm visual analogue scale bounded by the descriptors 'no shortness of breath at all' and 'maximum shortness of breath' and using the Medical Research Council (MRC) scale which specifies eight levels of dyspnoea.
3. Lung function testing:
Including forced spirometry with bronchodilator test with a Datospir 120 spirometer following Spanish Society of Pneumology and Thoracic Surgery (SEPAR) recommendations for the values of FVC, FEV1, FEV1/FVC and Finite Element Model (FEM).
4. Number of hospital admissions and length of stay:
By patient information. This information will be validated through hospital medical records.
5. Number of severe exacerbations:
Defined as episodes of either dyspnoea or dry or productive cough, whether sputum was purulent or not, treated with oral corticoids and/or antibiotics requiring hospital admission.

Overall study start date
10/03/2004

Completion date
15/06/2008

Eligibility

Key inclusion criteria
1. Clinical diagnosis of COPD with values of forced spirometry after broncodilatation of the ratio Forced Expiration Volume in 1 second (FEV1) / Forced Vital Capacity (FVC) less than 0.7 and FEV1 between 30% and 80% of its reference values (Global Initiative for Chronic Obstructive Lung Disease [GOLD] criteria of moderate COPD).
2. Age between 35 and 74 years old.
3. No experience of exacerbation or hospital admission in the month before inclusion.
4. Willingness to participate in the study and signed informed consent.

Smoking will not be considered as an exclusion criterion.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
97

Key exclusion criteria
1. Patients with severe and very mild COPD
2. FEV1<30% and >80%

3. Relevant osteoarticular disease or other debilitating diseases that could affect normal ambulation
4. Other important diseases that can impede follow-up (terminal patients, inmunodeficiencies, chronic infections)
5. Ischaemic heart disease, clinically evident, severe or uncontrolled systemic arterial hypertension.

Date of first enrolment
10/03/2004

Date of final enrolment
15/06/2008

Locations

Countries of recruitment
Spain

Study participating centre
Reina Esclaramunda 9
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Sponsor information

Organisation
TV3 Marathon Foundation (Fundació La Marató de TV3) (Spain)

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Sponsor type
Charity

Website
http://www.tv3.cat/marato/

ROR
https://ror.org/00t5xc355

Funder(s)

Funder type
Charity

Funder Name
TV3 2004 Marathon Foundation (Fundació Marató TV3 2004) (Spain)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/09/2006		Yes	No
Results article	results	11/02/2013		Yes	No