ISRCTN15106246 https://doi.org/10.1186/ISRCTN15106246

Educational intervention to improve the inhalation technique in patients with chronic obstructive pulmonary disease (COPD)

Submission date 23/03/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/04/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 19/05/2011	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

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

PI-0492/09 and EC10-193

Study information

Scientific Title
Efficacy of two educational interventions about inhalation technique in patients with chronic obstructive pulmonary disease (COPD): a preference study

Acronym
TECEPOC

Study objectives
The application of two educational interventions in patients with chronic obstructive pulmonary disease (COPD) with inhaled therapy is going to improve in at least 25% the patients who perform a correct inhalation technique.

Please note, as of 19/05/2011 a continuation of this trial has been implemented. The modifications to the trial can be found under the date of update in the relevant sections below. The anticipated end date has therefore been extended from 31/12/2011 to 30/06/2013.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethical Committee of Distrito Sanitario Málaga approved on the 1st March 2007
2. Ethical Committee of Distrito Sanitario Axarquía approved on the 13th May 2008

Study design
Multicentre patients' preference trial or comprehensive cohort design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions

Current interventions (as of 19/05/2011)
The study is divided into two groups and five arms. The two groups are:
1. The patients' preferences group (two arms)
2. The randomised group (three arms)

In the preferences group, the two arms correspond to the two educational interventions designed for this study. In the randomised group, the three arms are as follows:

Intervention A: Written information -
We will give written information about inhalation technique to the patient. We will design a leaflet about the correct inhalation technique, containing the main devices the patients use in our area.

Intervention B: Written information about inhalation technique and instructor training -
We will give written information about inhalation technique to the patient (leaflet described above) and we are going to train the patient about correct inhalation technique.

Control group:
Treatment as usual.

The appointments are approximately 20 - 30 minutes, depending on the arm of study. When the participant been located in an intervention arm the visit will be more detailed. The follow-up is the same for all arms and will be for 12 months.

Visit schedule:

Intervention Group A and B:
Visit of inclusion: all the study data will be recorded and the inhalator technique will be tested
Visit 1: It will take place 1 month after the intervention. Primary and secondary outcomes (not spirometry and quality of life) will be measured and encouraging work about inhalers techniques and motivational aspects related with this will be individually applied.
Visit 2: I will take place 3 months after the intervention. all the study data will be recorded and encouraging work about inhalers techniques and motivational aspects related with this will be individually applied.
Visit 3: It will take place 6 months after the intervention. Primary and secondary outcomes (not spirometry and quality of life) will be measured and encouraging work about inhalers techniques and motivational aspects related with this will be individually applied.
Visit 4: I will take place 12 months after the intervention. All the study data will be recorded and encouraging work about inhalers techniques and motivational aspects related with this will be individually applied.

Control Group:
Visit of inclusion: all the study data will be recorded and the inhalator technique will be tested.
Visit 1: It will take place 1 month after the intervention. Primary and secondary outcomes (not spirometry and quality of life) will be measured.
Visit 2: I will take place 3 months after the intervention. All the study data will be recorded.
Visit 3: It will take place 6 month after the intervention. Primary and secondary outcomes (not spirometry and quality of life) will be measured.
Visit 4: I will take place 12 months after the intervention. All the study data will be recorded.

Previous interventions:
The study is divided into two groups and five arms. The two groups are:

1. The patients' preferences group (two arms)
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Treatment as usual.

The appointments are approximately 20 - 30 minutes, depending on the arm of study. When the participant been located in an intervention arm the visit will be more detailed. The follow-up is the same for all arms and will be for 3 months.

Visit schedule:

Intervention Group A and B:
Visit of inclusion: all the study data will be recorded and the inhalator technique will be tested
Visit 1: It will take place 1 month after the intervention. Primary and secondary outcomes (not spirometry and quality of life) will be measured and encouraging work about inhalers techniques and motivational aspects related with this will be individually applied.
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Control Group:
Visit of inclusion: all the study data will be recorded and the inhalator technique will be tested.
Visit 1: It will take place 1 month after the intervention. Primary and secondary outcomes (not spirometry and quality of life) will be measured.
Visit 2: I will take place 3 months after the intervention. All the study data will be recorded.

Secondary Sponsor Details:
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Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Performance of correct inhalation technique. The correct inhalation technique will be measured by an investigator following SEPAR guidelines. Measured at all visits

Secondary outcome measures
Current secondary outcomes measures (as of 19/05/2011):

1. Pick flow, measured at all visits
2. Dyspnoea (Baseline Dyspnoea Index [IDB] and Modified Medical Research Council [MMRC] questionnaires), measured at all visits
3. Functional status (spirometry), measured at visit of inclusion, visit 2 and visit 4.
4. Quality of life, measured with the Spanish version of the St George's Respiratory Questionnaire and the specifically created SeguiEPOC Questionnaire, measured at visit of inclusion, visit 2 and visit 4.

Previous secondary outcome measures:

1. Pick flow, measured at all visits
2. Dyspnoea (Baseline Dyspnoea Index [IDB] and Modified Medical Research Council [MMRC] questionnaires), measured at all visits
3. Functional status (spirometry), measured at visit of inclusion and visit 2
4. Quality of life, measured with the Spanish version of the St George's Respiratory Questionnaire and the specifically created SeguiEPOC Questionnaire, measured at visit of inclusion and visit 2

Overall study start date
15/03/2010

Completion date
30/06/2013

Eligibility

Key inclusion criteria
1. Confirmed COPD diagnose by spirometry (Spanish Society of Pulmonology and Thoracic Surgery [SEPAR] guidelines)
2. Belonging to the selected Primary Care Centres in Malaga area
3. Use of inhalatory therapy
4. Accepted to participate in the study and gives informed consent
5. Aged greater than or equal to 18 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
495

Key exclusion criteria
1. Diagnosis of other respiratory conditions which are not included in the COPD definition
2. Cognitive impairment problems

Date of first enrolment
15/03/2010

Date of final enrolment
30/06/2013

Locations

Countries of recruitment
Spain

Study participating centre
Unidad Docente Medicina Familiar y Comunitaria
Málaga
Spain
29009

Sponsor information

Organisation
Council of Andalusian Health Services (Consejería de Salud, Junta de Andalucia) (Spain)

Sponsor details
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Sponsor type

Government

Website
http://www.juntadeandalucia.es/index.html

ROR
https://ror.org/03q4c3e69

Funder(s)

Funder type
Government

Funder Name
Council of Andalusian Health Services (Consejería de Salud, Junta de Andalucia) (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