

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/05/2011	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

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: It 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: It 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: It 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: It 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)
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 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.

Visit 2: It 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.

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: It will take place 3 months after the intervention. All the study data will be recorded.

Secondary Sponsor Details:

Dirección General de Farmacia y Productos Sanitarios de Ministerio de Sanidad, Política Social e Igualdad. (Spain)

Paseo del Prado 18-20

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28014

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+34 915961000

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<http://www.msps.es>

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 Andalucía) (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 Andalucía) (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