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

Submission date 06/07/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 04/08/2011	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 11/02/2016	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
An inhaler is a device holding a medicine that you take by breathing in (inhaling). The delivery of drugs through inhalers has revolutionized the treatment of patients with respiratory (lung) diseases. The effectiveness of inhaled drugs can be influenced by many factors including age, sex, educational level, duration of the disease, type of inhaler, a correct technique or the use of multiple devices. Misuse of inhalers is a significant problem both for asthma and chronic obstructive pulmonary disease (COPD) because the consequence is a decrease in the effect of the drugs, causing a worse control of symptoms and therefore no effective control of the disease. The aim of this study is to evaluate the effectiveness of two educational interventions to improve the technique of drug inhalation in patients with COPD.

Who can participate?
Patients aged over 18 diagnosed with COPD who use inhaled therapy.

What does the study involve?
Participants are randomly allocated into three groups. The first group receives a leaflet about the correct inhalation technique. The second group receives the same leaflet and also instructor training about the correct inhalation technique. The third group receives treatment as usual. All participants attend follow-up appointments 3, 6 and 12 months later. The appointments are about 20 - 30 minutes long, depending on the group.

What are the possible benefits and risks of participating?
There are no risks for the participants

Where is the study run from?
Primary care centres in Málaga (Spain)

When is the study starting and how long is it expected to run for?
March 2011 to December 2013

Who is funding the study?
Instituto de Salud Carlos III (Ministerio de Ciencia e Innovación, Gobierno de España) (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PI10/02384

Study information

Scientific Title
Efficacy of two educational interventions about inhalation technique in patients with Chronic Obstructive Pulmonary Disease (COPD) - a randomized controlled trial

Acronym
TIEPOC

Study objectives
The application of two educational interventions in patients with COPD who use inhaled therapy will increase the number of patients who perform a correct inhalation technique by at least 25%

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Ethical Committees of Distrito Sanitario Málaga, 21/12/2010
2. Área Sanitaria Málaga Este-Axarquía, 16/02/2010
3. Autonomic Clinical Assays Committee, 25/01/2011

Study design
Multicenter randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
The study is divided into three arms by block randomization: control, intervention A and intervention B:
1. Intervention A: written information
1.1. We will give written information about inhalation technique to the patient
1.2. We will design a leaflet about the correct inhalation technique, containing the main devices that patients use in our area
2. Intervention B: written information about inhalation technique and instructor training
2.1. We will give written information about inhalation technique to the patient (leaflet described above) and we are going to train the patient about the correct inhalation technique
3. Control group: treatment as usual
4. The appointments are approximately 20 - 30 minutes, depending on the arm of study
5. When the participant been located in an intervention arm the visit will be more detailed
6. 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 3 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 2: 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 3: 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 3 months after the intervention. Primary and secondary outcomes (not spirometry and quality of life) will be measured.
Visit 2: It will take place 6 months after the intervention. Primary and secondary outcomes (not spirometry and quality of life) will be measured.
Visit 3: I will take place 12 months after the intervention. All the study data will be recorded.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Performance of correct inhalation technique
2. The correct inhalation technique will be measured by an investigator following SEPAR guidelines

Key secondary outcome(s))
1. Pick flow measured at all visits
2. Dyspnea (Baseline dyspnea 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 (St George and SeguiEPOC questionnaires), measured at visit of inclusion, visit 2 and visit 4

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Confirmed COPD diagnosis by spirometry (SEPAR guidelines)
2. Belonging to the selected Primary Care Centers in Malaga area
3. Use of inhaled therapy
4. Accepted to participate in the study and given informed consent
5. Aged over 18 years
6. Male or female participants

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
15/09/2011

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Spain

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

Sponsor information

Organisation
Instituto de Salud (Instituto de Salud Carlos III, MInisterio de Ciencia e Innovación) (Spain)

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Government

Funder Name
Instituto de Salud (Instituto de Salud Carlos III, MInisterio de Ciencia e Innovación) (Spain)

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes