

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

Submission date 06/07/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/08/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/02/2016	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?
Dr D. José Leiva Fernández
mariap.barnestein.exts@juntadeandalucia.es

Contact information

Type(s)
Scientific

Contact name
Dr José Leiva Fernandez

Contact details
Unidad Docente Medicina Familiar y Comunitaria
Distrito Sanitario Málaga
Plaza Hospital Civil s/n Pabellón 6 2ª planta
Málaga
Spain
29009
+34 (0)951 290 310
mariap.barnestein.exts@juntadeandalucia.es

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

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: 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 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: It will take place 12 months after the intervention. All the study data will be recorded.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Performance of correct inhalation technique
2. The correct inhalation technique will be measured by an investigator following SEPAR guidelines

Secondary outcome measures

1. Peak 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

Overall study start date

15/03/2011

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

296

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)

Sponsor details

Sinesio Delgado nº 6

Madrid

Spain

28029

+34 (0)918 222 100

oficina.informacion@isciii.es

Sponsor type

Government

Website

<http://www.isciii.es>

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**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