Study evaluating preference, satisfaction and ease of use of inhalers in COPD diagnosed patients

Published: 27-04-2011
Last updated: 27-04-2024

to assess patient's overall preference for the two inhaler devices in COPD patients after 2 weeks of dialy practice.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON35964

Source
ToetsingOnline

Brief title
Genuair

Condition

- Respiratory disorders NEC

Synonym
chronic obstructive lung disease, smokers lung

Research involving
Human

Sponsors and support

Primary sponsor: Almirall
Source(s) of monetary or material Support: Farmaceutisch bedrijf Almirall S.A.

Intervention

Keyword: COPD patients, Inhalation, International clinical study, Medical devices study

Outcome measures

Primary outcome

The primary variable is the percentage of patients who prefer the new inhaler

at visit 2.

Secondary outcome

The secundary outcome

ease of use

convenience

ease of learning to use

ease of holding

ease of operating

ease of preparation of the dose

feedback to indicate correct inhalation

dosage

Study description

Background summary

Because an inadequate technique reduces the effect of inhalation, the development of an easy-to-use inhaler device that delivers effectively the drug to the lungs, is as important as the development of an efficacious and safe drug itself. It is of clinical interest to run this study to evaluate patient's preferrence, satisfaction and ease of use, on the use of inhalers, in COPD diagnosed patients in order to gain better knowledge of how these patients perform on the use of these inhalers and the potential benefits the results

migt bring.

Study objective

to assess patient's overall preference for the two inhaler devices in COPD patients after 2 weeks of dialy practice.

Study design

Randomized, cross-over multinational and multicentre design with two measurement moments, both devices will contain only placebo

Intervention

Not applicable

Study burden and risks

Two visits and during the second visit the subjects will be asked to fill out a questionnaire. In between the two visits, the subjects will be using two additional inhalers dialy and will be fillling out a patient diary.

Contacts

Public
Almirall

Rda. General Mitre, 151
08022 Barcelona
ES
Scientific
Almirall

Rda. General Mitre, 151
08022 Barcelona
ES

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

male or female aged > 39 years
stable COPD
naïve to the study inhalers

Exclusion criteria

clinical significant disease, particular body malformations of diseases affecting coordination and/or motor system (e.g. malformations or lack of upper extremities, Any disease that may affect the proper handling of the inhalers (Wilson*s disease, Stroke, Parkinson, Huntington*s Chorea...) ;unable to read product package instructions and to answer questionnaires

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-06-2011
Enrollment:	60

Type:	Actual

Medical products/devices used

Generic name:	Genuair Inhaler
Registration:	No

Ethics review

Approved WMO Date:	27-04-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	29-09-2011
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL35663.044.11