Study evaluating ease of use, preference and satisfaction of two different Fluticason/salmeterol inhalers in asthma or COPD patients

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To assess the percentage of COPD and asthma patients correctly (all critical items correct) using the Accuhaler/Diskus vs Elpenhaler inhaler devices after reading the package insert. Also satisfaction with and preference for an inhaler will be...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON35747

Source
ToetsingOnline

Brief title
Ease of use of two inhalers

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Asthma, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: Er is voor deze studie een unrestricted grant van GlaxoSmithKline ontvangen,GlaxoSmithKline

Intervention

Keyword: COPD, Inhalation technique, Patient preference

Outcome measures

Primary outcome

The percentage of COPD and asthma patients correctly (all critical items

correct) using the Accuhaler/Diskus vs Elpenhaler inhaler devices after reading

the package insert

Secondary outcome

To assess patient*s overall satisfaction with each device.

To assess the number of instructions needed for correct use of each device

To assess the patient*s overall preference for a device

Study description

Background summary

Inhalation therapy is the main method of administering medication to patients with asthma or COPD. It is important that patients are instructed in the use of their inhalers. this study investigates how easy it is to instruct and use two different inhalers and which inhaler patients prefer. An inhaler that is easy to use will lead to a better inhalation technique and fewer inhalation errors. This, in turn, will lead to a better effectiveness of the medication. A better effectiveness, coupled with a stronger preference for an inhaler will lead to better therapy adherence.

Study objective

To assess the percentage of COPD and asthma patients correctly (all critical items correct) using the Accuhaler/Diskus vs Elpenhaler inhaler devices after reading the package insert. Also satisfaction with and preference for an inhaler will be assessed as well as the number of instructions needed to reach

an adequate inhalation technique.

Study design

Multi-center randomised cross-over study

Intervention

Patients will be asked to demonstrate their proficiency with two different inhalers, after reading the package insert, and, if errors are observed, after up to three instructions.

Study burden and risks

The burden exists of demonstrating the use of two inhalers after reading the package insert, and possible follow-up instructions. There is no risk associated with the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Age > 40 with stable COPD or asthma
2. Patients naïve to the study inhalers, Accuhaler/Diskus and Elpenhaler for at least 1 year
3. Patients agreeing on participating and signing the Informed Consent Form

Exclusion criteria

1. Patients currently participating in another randomised clinical trial
2. Patients with body malformations or diseases affecting coordination and/or motor system
3. Patients unable to read product package instructions and answer patient reported questionnaires

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-12-2011
Enrollment:	110
Type:	Actual

Medical products/devices used

Generic name:	Diskus/Accuhaler Inhaler / Elpenhaler
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-11-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	27-03-2012
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	NL37382.044.11