# 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

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

## Ethics review

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|---|---|
| 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 |