Onderzoek naar gebruiksgemak van, voorkeur voor, en tevredenheid met twee verschillende inhalatoren bij patiënten met astma of COPD.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21792

Source
NTR

Brief title
Diskus versus Elpenhaler

Health condition

asthma
astma
COPD
chronische bronchitis
longemfyseem

Sponsors and support

Primary sponsor: Medisch Spectrum Twente, Enschede
Source(s) of monetary or material Support: GlaxoSmithKline

Intervention

Outcome measures

Primary outcome

Percentage of patients doing at least 1 critical error using each device after reading the insert.

Secondary outcome

1. Percentage of patients doing at least 1 critical error using each device after the first instruction by the trainer;

2. Number of instructions needed;

3. Overall satisfaction with the device;

4. The percentage of patients who prefer Accuhaler/Diskus.

Study description

Background summary

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

Primary Objective:

To compare 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 Objectives:

1. To compare patient’s overall satisfaction with each device;

2. To compare the number of instructions needed for correct use of each device;

3. To compare the patient’s overall preference for a device.

Study Design:

Randomized cross-over multinational and multicentre design with one measurement moment; both devices will contain only placebo.

Study Population:

A total of 110 subjects, 55 subjects per sequence, will be randomized.

Evaluations:

Correct use, patient’s preference and satisfaction will be evaluated using the inhaler devices with placebo.

Study objective

Diskus is superior to Elpenhaler with regard to ease of use, preference and satisfaction.

Study design

The study consists of 1 visit.

Intervention

Randomized cross-over multicentre design with one measurement moment; both devices will contain only placebo.

The subjects will be randomly distributed into 2 groups, determining the sequence of use of each inhaler: patients in Group A will use Accuhaler/Diskus device first and secondly the Elpenhaler. Patients in Group B will use Elpenhaler first followed by Accuhaler/Diskus.

The study consists of 1 visit. First, the patient will be asked to read the written package insert of the first device according to the sequence of Group A or B, which is followed by a first attempt. If any mistake in inhalation is made patients will be instructed by a trainer in the device (up to 4 attempts).

Contacts

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Eligibility criteria

Inclusion criteria

1. Adult male or female patients aged > 40 with stable COPD or asthma;

2. Patients have to be 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 type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-08-2011
Enrollment:	110
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-07-2011
Application type:	First submission

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
NTR-new	NL2847
NTR-old	NTR2989
Other	METC / CCMO : P11-26 / NL37382.044.11;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A