A randomized, open-label, cross-over, placebo-device study investigating critical and over all errors, training/teaching time, and preference attributes of the ELLIPTA dry powder Inhaler (DPI) as compared to HandiHaler DPI used in combination with either DISKUS DPI or Turbuhaler DPI, in adult patients with Chronic Obstructive Pulmonary Disease (COPD) (study 206215)

Published: 09-12-2016
Last updated: 11-04-2024

Primary:To compare the number of critical errors made by COPD patients, after a subject has read the respective patient information leaflet(s) (PIL), for each treatment option tested.Secondary:Number of critical errors made after instruction from...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON45492

Source
ToetsingOnline

Brief title
study 206215

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic obstructive airways disease (COPD)

Research involving
Human

Sponsors and support

Primary sponsor: GlaxoSmithKline
Source(s) of monetary or material Support: GlaxoSmithKline BV

Intervention

Keyword: comparison, dry powder inhaler, ELLIPTA

Outcome measures

Primary outcome

The percentage of subjects making at least one critical error after reading the PIL(s).

Secondary outcome

Percentage of subjects making at least one critical error after the first / second instruction, percentage of subjects making at least one overall error after reading the PIL(s) / after the 1st instruction / after the 2nd instruction, number of instructions (0, 1 or 2 times) needed to demonstrate correct inhaler use, amount of time taken to demonstrate correct inhaler use (T1+T2), to read the PIL and demonstrate correct inhaler use (T1), to be given instruction and to demonstrate correct inhaler use (T2), Treatment preference for: number of steps required to take COPD medication and overall treatment

preference.

Study description

Background summary

Currently, subjects requiring triple therapy can be prescribed ICS/LABA and LAMA in separate inhalers. The specific ICS/LABA and LAMA prescribed determine whether the inhaler types (and thereby the inhalation techniques) and the dosing regimens are similar or different. Use of different inhaler types with different inhalation techniques and dosing regimens can add to treatment complexity, and also increase the potential for errors in inhaler use that reduce or preclude drug delivery to the site of action in the lungs. Fixed-dose combination inhalers that minimize the number of inhalers required would simplify treatment, improve adherence, reduce errors in inhaler use, and potentially lead to better treatment outcomes.
This study is designed to assess the benefits of delivering triple therapy using one single ELLIPTA DPI (Dry Powder Inhaler) versus delivering triple therapy using two different types of inhalers to patients with COPD. It will assess the proportion of COPD subjects who make critical errors when using one single ELLIPTA DPI versus those using combinations of commercially available and commonly used DPIs: DISKUS used in combination with HandiHaler, or Turbuhaler used in combination with HandiHaler. This study would also assess training/teaching time and preference attributes for closed triple therapy as compared to the open triple therapy.

Study objective

Primary:
To compare the number of critical errors made by COPD patients, after a subject has read the respective patient information leaflet(s) (PIL), for each treatment option tested.
Secondary:
Number of critical errors made after instruction from the healthcare provider, number of (non)critical errors after reading the PIL(S) or after Instruction, number of instructions needed to demonstrate correct inhaler use, Training/Teaching Time required to demonstrate correct inhaler use, patient preference.

Study design

Randomized, open-label, placebo-device, cross-over study, with a 2x2 complete block design.
Sub-study 1: ELLIPTA DPI versus DISKUS-HandiHaler DPI combination.

Sub-study 2: ELLIPTA DPI versus Turbuhaler-HandiHaler DPI combination.
Allocation to sub-studies: based on the type(s) of inhaler used in the past 2 years.
Randomization for treatment sequence.
Each sub-study may run independently or in parallel of the other sub study.
Approximately 144 evaluable complete subjects.

Intervention

Placebo-inhalations from 3 inhalers.

Study burden and risks

Risk: Adverse events of the placebo ingredients. No active study medication.
Burden:
1 visit, approx. 2 hours duration.
Up to 3 attempts to demonstrate the correct use of each of the 3 inhalers:
Attempt 1
Read the PIL of the inhaler. Demonstrate how to use that inhaler. Any errors will be recorded. If no errors: continue with next inhaler.
Attempt 2
In case of error(s) in attempt 1, study staff instruct the subject in correct use of the inhaler. Demonstrate how to use that inhaler. Any errors will be recorded. If no errors: continue with next inhaler.
Attempt 3
In case of error(s) in attempt 2, study staff instruct the subject again in correct use of the inhaler. Demonstrate how to use that inhaler. Any errors will be recorded. Always (with or without errors): continue with next inhaler.
Patient preference (2 questions).

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

* *40 years of age.
* COPD in accordance with the definition by the European Respiratory Society.
* Currently receiving maintenance therapy with a fixed dose combination of a long-acting beta 2-agonist and inhaled corticosteroid for at least 4 weeks, ± long-acting anti-cholinergic.
* Current or former cigarette smokers with a >10 pack-year smoking history.
* Males or females who are not pregnant or not lactating.

Exclusion criteria

* Asthma.
* Use of the ELLIPTA inhaler in the past 24 months.
* Use of any capsule system inhaler in the past 24 months, examples see protocol page 16).
* Use in the past 24 months of DISKUS (for sub-study 1) or Turbuhaler (for sub-study 2).
* History of hypersensitivity to lactose, magnesium stearate. History of severe milk protein allergy that, in the opinion of the study physician, contraindicates participation.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	125
Type:	Actual

Ethics review

Approved WMO Date:	09-12-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-04-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL59648.100.16
Other	www.gskclinicalstudyregister.com (206215)