A randomized, multi-center, open-label, cross-over study comparing critical errors, overall errors, training/teaching time, and preference attributes of the ELLIPTA dry powder inhaler versus the BREEZHALER dry powder inhalers, in adult participants with mild to moderate asthma.

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Primary objective:To compare the proportion of participants who make at least one critical error after reading the section on inhaler use in the patient information leaflets (PILs) for ELLIPTA and BREEZHALER inhalersSecondary Objectives:To compare...

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

Summary

ID

NL-OMON50806

Source
ToetsingOnline

Brief title
213306 - Ellipta Device

Condition

- Respiratory disorders NEC

Synonym
Asthma;dry powder inhaler

Research involving
Human

Sponsors and support

Primary sponsor: GlaxoSmithKline
Source(s) of monetary or material Support: GlaxoSmithKline B.V.

Intervention

Keyword: Asthma, Breezhaler, Critical errors, Ellipta

Outcome measures

Primary outcome

The proportion of participants who make at least one critical error in each inhaler (ELLIPTA or BREEZHALER) after reading the section on inhaler use in the PIL(s).

Secondary outcome

Participants who still make at least one critical error after receiving further instruction (up to 3) from the HCP. Participants receive further instruction if an error was made after reading the PIL.

Participants who make at least one overall error after reading the PIL(s) (Attempt 1).

This will be repeated for the participants who still make at least one overall error after receiving further instruction (up to 3) from the HCP. Participants receive further instruction if an error was made after reading the PIL.

Errors (critical and overall) made after reading the PIL(s), and, if necessary, after receiving further instruction from the HCP.

The amount of time taken to demonstrate inhaler use without HCP intervention.
The amount of time taken to be given instruction by the HCP (up to 3 times) on use of the inhaler and to demonstrate inhaler use.

Ease-of-use preference from questionnaire, that is, how the ease of use is rated (very easy, easy, neutral, difficult or very difficult). The variables will include the:

* Variable: Ease of use rating.
* Population-summary measure: the number and percentage of participants who rate the inhaler.

The population-summary measure defined above will be the same for the following variables as indicated by participants* ease of use:

* Telling how many doses are left in Inhaler
* Learning how to use the inhaler
* Handling the inhaler
* Preparing the inhaler
* Holding the inhaler while using it

Willingness to continue with the inhaler using a visual analogue scale (VAS) between 0 (not willing) to 100 (definitely willing).

Participants who expressed a preference on attributes from the preference questionnaire. The number and percentage of participants who prefer the respective inhaler overall (ELLIPTA, BREEZHALER or no preference).

Study description

Background summary

The importance of correct use of inhalers is emphasised by GINA for asthma patients and by GOLD for patients with chronic obstructive pulmonary disease (COPD) by ensuring selection of the appropriate inhaler, demonstration of the inhaler and assessment of inhaler use is reviewed prior to escalating therapy. Errors made by the patient can affect the amount of medication received and disease control so it is essential to ensure good inhaler technique.
Comparison of inhaler techniques between asthma and COPD patients suggests some inconsistencies with some observational studies demonstrating similar error rates and other studies demonstrating higher rates in COPD patients but when adjusting for age, inhaler and level of instruction, this difference disappeared. Study designs often observational, in usual practice with patients being familiar with their inhalers, in different geographical and socio-economic areas may account for the inconsistent effects. Older, lower socio-economic and educational levels and female gender were risk factors for greater errors in inhaler handling.
The ELLIPTA DPI was developed to deliver various inhaled maintenance medications, including mono, dual and triple therapies, for the treatment of asthma and COPD. ELLIPTA has been designed to be simple to use. Participants with asthma or COPD make fewer critical errors (defined as an error that is most likely to result in no or significantly reduced medication being inhaled) and overall errors (any error in inhaler technique) with the ELLIPTA DPI than with other DPIs. Furthermore, participant preference for the ELLIPTA DPI has been demonstrated previously versus other DPIs for many attributes, including ease of use and time to train. The BREEZHALER DPI is also approved for use with a variety of inhaled mono- or combination-medications although BREEZHALER has not been widely used by asthma patients.
The study involves the use of placebo DPI inhalers (placebo ELLIPTA and BREEZHALER) that do not contain active treatments. Participants will continue to take their own prescribed asthma medication and other concomitant medication during the study. Participants should also follow-up with their regular physician for their asthma healthcare during the study.
The placebo inhaler for ELLIPTA and the placebo capsules for BREEZHALER contain the excipients lactose.

Study objective

Primary objective:
To compare the proportion of participants who make at least one critical error after reading the section on inhaler use in the patient information leaflets (PILs) for ELLIPTA and BREEZHALER inhalers

Secondary Objectives:
To compare the proportion of participants who still make at least one critical error after receiving further instruction from the Healthcare Professional (HCP) for ELLIPTA and BREEZHALER inhalers

To compare the proportion of overall errors made by the participants after reading the PIL, and if necessary, with additional instruction from the HCP for ELLIPTA and BREEZHALER inhalers

To summarise the number of errors (critical and overall) made on each inhaler, with or without further HCP instruction.

To compare the proportion of participants that require further instruction from the HCP to demonstrate correct inhaler use for ELLIPTA and BREEZHALER inhalers

To compare the Training/Teaching Time required to demonstrate correct inhaler use for ELLIPTA and BREEZHALER inhalers.

To compare ease-of-use for ELLIPTA and BREEZHALER inhalers

To summarise ease-of-use for ELLIPTA and BREEZHALER inhalers

To compare the willingness to continue with the ELLIPTA and/or BREEZHALER inhaler

To compare preference attributes for ELLIPTA and BREEZHALER inhalers

Study design

The study will be a randomized, multi-center, open label, placebo study with a 2x2 complete block crossover design. The study will have one visit (although there could be two visits with up to 30 days between the informed consent visit (V0) and the study intervention visit (V1).
Eligible participants with mild to moderate asthma will be randomized to test either the ELLIPTA DPI (containing placebo) followed by BREEZHALER DPI (with placebo capsules), or vice versa in each of the two blocks for the crossover study. Only participants who are naïve to both ELLIPTA and BREEZHALER inhaler will be included.

Participants will demonstrate inhaler use for the first inhaler after reading the relevant sections of the PIL (Attempt 1). If the participant makes any errors, the investigator demonstrates the correct use of the inhaler by conducting a full demonstration as described in the relevant section of the PIL, and the participant will try inhaler use again (Attempt 2). If after the first demonstration by the investigator the participant continues to make errors, the investigator will demonstrate correct inhaler use to the participant up to two additional times (Attempts 3 & 4).

Following each attempted use of the inhaler by the participant, the trained investigator will assess for and document any critical errors (i.e. defined as an error that is most likely to result in no or significantly reduced medication being inhaled) and non-critical errors made by the participant. This process of error assessment will be used to assess for critical and non-critical errors made by the participant for both inhalers being tested.
At the end of the assessment of the first inhaler, participants will be asked to complete the ease-of-use questionnaire for this device followed by participant completion of the visual analogue scale (VAS) on their willingness to continue with this inhaler.

Participants will be permitted up to a 30-minute break (if required) between completing the assessment of the first inhaler and commencing error assessments for the second inhaler. The second inhaler critical errors assessment follows the same sequence of testing as the first * (Attempts 1 is with no HCP instruction and Attempts 2-4 are with HCP instruction as required).
Once the error assessment of the second inhaler has been completed the participant will complete the ease-of-use questionnaire for this device followed by participant completion of the visual analogue scale (VAS) on their willingness to continue with this inhaler.

If required, another period of up to 30 min for a break would be allowed followed by the participant completing one of the two versions of the preference questionnaire, as per randomization sequence.
Two versions of the inhaler preference questionnaire are provided to minimise any potential bias introduced from the order in which the inhalers are taken in relation to the order the inhalers are assessed by the participant in each questionnaire. The version of each questionnaire to be completed by each participant is determined by the sequence arm they are randomly assigned to at Visit 1.

Intervention

inhalation of a placebo from a dry powder inhaler

Study burden and risks

As with other inhalation therapy, paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. From post-marketing data from FF/VI, paradoxical bronchospasm has been reported at a frequency of <1/10,000 including isolated reports.
The placebo inhaler for ELLIPTA and the placebo capsules for BREEZHALER contain the excipient lactose. There are known allergies to this ingredient.
Participants with a known hypersensitivity to this or severe milk protein allergy are excluded from 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

Participant must be aged 18 years or older
Participants who have a confirmed mild or moderate asthma diagnosis

Participants must be on asthma maintenance therapy (ICS or ICS/LABA) for at least 12 weeks prior to study participation.
Participants must be naïve to both the ELLIPTA and BREEZHALER inhalers

Exclusion criteria

Concurrent diagnosis of COPD or other respiratory disorders including active tuberculosis, lung cancer, bronchiectasis, sarcoidosis, lung fibrosis, pulmonary hypertension, interstitial lung diseases or other active pulmonary diseases.
History of hypersensitivity to any components of the study inhaler (e.g., lactose).
Historical or current evidence of clinically significant or rapidly progressing or unstable disease that would put the safety of the participant at risk through participation, or which would affect the analysis if the disease/condition exacerbated during the study.
Participants with a known or suspected alcohol or drug abuse.
Any participant who is unable to read and/or would not be able to complete a questionnaire and understand verbal instructions.
Medical and physical conditions that could impact the ability of the participant to manipulate the inhaler

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	14-04-2021
Enrollment:	114

Type:	Actual

Medical products/devices used

Generic name:	Ellipta
Registration:	No

Ethics review

Approved WMO Date:	29-03-2021
Application type:	First submission
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
Other	https://www.trialsummaries.com nummer 213306
CCMO	NL76067.100.21

Study results

Date completed:	08-07-2021
Results posted:	31-01-2022

First publication
16-12-2021