Study Evaluating the Added Value of the Triple Feedback Mechanism of the NEXThaler by focusing on Critical ErrOrs, PRefeRencEs and SatisfaCTion with the NEXThaler versus a non-feedback providing dry powder inhaler in Asthma an COPD patients

Published: 13-11-2019
Last updated: 06-05-2024

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

Summary

ID

NL-OMON55778

Source
ToetsingOnline

Brief title
CORRECT

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: Chiesi Pharmaceuticals

Intervention

Keyword: Astma and COPD, Ciritcal errors, Device preference, Feedback mechanism

Outcome measures

Primary outcome

To compare the percentage of asthma and COPD patients performing all critical inhalation items correctly with the NEXThaler vs the Turbuhaler after 4 weeks of twice daily use of both inhalers.

Secondary outcome

To compare the number of instructions and time needed to achieve correct use of each device (all inhalation correct) at the first visit.

To assess the patients* satisfaction, willingness to continue and overall preference for NEXThaler vs. Turbuhaler inhaler devices after 4 weeks of daily use of both inhalers.

Build a prediction model (patient characteristics and literacy assessment) for sustainability of the inhalation technique.

Study description

Background summary

The effectiveness of inhaled medications in asthma and COPD is strongly influenced by the compliance to these medications. The choice and design of the

inhalation device plays a significant role in the effectiveness of inhaler therapy. Poor efficacy can be caused by a decreased medication delivery associated with an incorrect inhaler technique for the device being used. When patients are prescribed an inhaler, the choice should in part be based on how easy an inhaler is to use, and training to minimise errors in the use of the device.
A correct inhalation is as important as the development of an efficaious and safe drug. The NEXThaler is able to provide users feedback through three different mechanisms, users are able to verify whether their inhalation is performed at all and performed correctly. It is assumable that this triple feedback mechanisms provide added value above other inhalers lacking these mechanisms, resulting in a higher percentage of patients performing the inhalation correctly and with less instruction time needed after one month of actual use. However plausible as it sounds, this has not yet been investigated in a clinical setting.

Study objective

This study is designed to assess the proportion of asthma and COPD subjects making critical and non-critical errors in using NEXThaler compared with Turbuhaler after 4 weeks of clinical use. This will give insight in the importance of triple feedback mechanisms in an inhaler device. This study will also compare the ease of use and preference of NEXThaler compared to Turbuhaler.

Study design

An interventional, open-label, randomized, cross-over, 2-arm, multi-center study.

Intervention

Patients are asked to use 2 different inhalers in both study arms They will be asked to read the instructions for use of the inhaler and to demonstrate the use of the inhaler (with placebo) after instruction by the research assistant. Here the number of required instructions, time and critical errors are noted. The patient will use both inhalers at home for a period of 4 weeks. The ICS/LABA combination in the NEXThaler with beclomethasone/formterol 100/6 two inhalations twice daily is equivalent to the Turbuhaler with budesonide/formoterol 200/6 two inhalations twice a day.
At the end of the study the patient will be asked to ease of use and preference of NEXThaler compared to Turbuhaler

Study burden and risks

Patients come extra to the hospital with a maximum of 4 times, during these

visits the patient will read the manual, receive instructions and demonstrate the use of both inhalers.
The overall potential risk in this study is minimal due to the nature of the study; both inhalers are available on a commercial market and have a broad base experience.

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. Informed consent:
• Subject must give their signed and dated written informed consent to participate
• Subject understands and is willing, able, and likely to comply with study procedures

and restrictions
• Subject must be able to read, comprehend, and record information in Dutch
2. Age: >=18 years of age
3. Gender: male or female subjects (sex-ratio may not exceed 25% : 75%, either way)
4. Clinical diagnosis of Asthma or clinical diagnsosis of COPD (Gold I-IV). Comorbidities
(rheumatoid arthritis or other locomotor problems, visual impairment, and depression or anxiety)
will be documented as relevant to inhaler use
5. Asthma or COPD status and treatment: stable, well controlled on current medication
treatment with use of ICS and LABA or an indication (following GOLD en GINA criteria) or the
use of ICS/LABA combination
6. Must be naive for using the NEXThaler and TurbuHaler for the last 2 years

Exclusion criteria

1. Treatment with monoclonal antibodies (omalizumab, mepolizumab, benralizumab and
reslizumab)
2. Body malformations or diseases affecting coordination and/or motor systems necessary for
adequately using inhalation devices
3. Intolerance for any of the medication substances
4. Subjects who are currently participating in another randomised pharmacological inter-ventional
trial
5. Inability to read or answer patient reported questionnaires and manuals
6. Lactose intolerantie
7. Pregnant or giving breastfeeding

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-12-2019
Enrollment:	171
Type:	Actual

Ethics review

Approved WMO Date:	13-11-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-02-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-09-2021
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	NL69067.100.19