Evaluating the effect of qualitative feedback on asthma control in adults with difficult to treat asthma by improving therapy adherence and inhalation technique

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The primary objective of this study is to improve asthma control in adults with difficult to treat asthma, by increasing therapy adherence and inhalation technique with qualitative feedback.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Congenital respiratory tract disorders
Study type	Interventional

Summary

ID

NL-OMON48192

Source
ToetsingOnline

Brief title
IMAGINE II

Condition

- Congenital respiratory tract disorders

Synonym
asthma, bronchospasms

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Stichting Astmabestrijding

Intervention

Keyword: adherence, asthma, feedback, monitoring

Outcome measures

Primary outcome

The main study parameter is clinical improvement in asthma control in patients with difficult to treat asthma between phase 1 and phase 2 and the course of asthma control in phase 3. Clinical improvement in asthma control is assessed by a lung function test, the ACQ score and the AQLQ score.

Secondary outcome

Secondary study parameters include the therapy adherence and inhalation technique. Therapy adherence is the rate of which the patient takes his inhalation medication at the appropriate frequency time. If the therapy adherence rate equals or exceeds the 75% (subjects take their medication twice daily in 75% or more percent of the days), the patient is considered therapy adherent. Next to the dichotomous way of measuring adherence, patients will also be classed in underuser (<50%), suboptimal users (50-<75%), optimal users(75-125) and overusers (>125%) based on adherence rates.24 Inhalation technique is defined as the amount of times a patient inhales the medication correctly with regard to technique of the inhalation and orientation of the inhaler. To be able to determine the therapy adherence and inhalation technique, date and time of inhalation, the position of the device during

inhalation, peak flow, the duration of the inhalation, the total volume and opening and closing of the device will be measured. All (critical) errors made will be recorded. Furthermore, after phase 1, patient factors related to poor adherence are determined. These are included in the secondary study parameters and their role in the therapy adherence will be assessed.

FeNO will be measured using a NIOX MINO (Aerocrine AB, Stockholm, Sweden) according to American Thoracic Society/European Respiratory Society recommendations at a 50 ml/s flow rate.25 FeNo will be measured at inclusion and at the end of phase 2.

Blood eosinophil count will be measured at inclusion (or in case this was measured less than 3 months before inclusion, the latter measurement will be used as baseline eosinophil count) and at the end of phase 2. Blood eosinophil count will be expressed as a continous measure as well as above or below the cut-off of the eosinophilic (blood eosinophil count >=0.3×109 L*1; suitable for anti-IL-5 therapy) or allergic phenotype (serum IgE level >=30 kU·mL*1).26

Study description

Background summary

Severe uncontrolled asthma is associated with substantial morbidity and health care costs. Before prescribing expensive add-on therapies (e.g. biologicals) clinicians should address adherence to therapy and inhaler technique. Previous studies have shown that around 50% of patient with difficult to treat asthma is not adherent to medication. In this study, the effect of providing qualitative feedback on therapy adherence and inhalation technique is assessed.

Study objective

The primary objective of this study is to improve asthma control in adults with

difficult to treat asthma, by increasing therapy adherence and inhalation technique with qualitative feedback.

Study design

The first phase consists of a 1 month observational study period, where the therapy adherence and inhalation technique of the patients is assessed. Parameters related to poor adherence are determined in this phase. The second phase of 3 months consists of a randomised controlled trial where one group receives qualitative feedback on therapy adherence and inhalation technique and the other group does not receive feedback. Finally, in phase 3, the lasting effect of qualitative feedback will be assessed. This phase is an observational follow-up traject in which the feedback will be ceased for all patients and revision of current therapy may occur, depending on findings in phase 2

Intervention

For this study, a Respiro¬TM add-on device is attached to the current inhaler therapy to measure parameters such as date and time of inhalation, orientation of the inhaler, peak flow, duration of the inhalation,volume of flow and opening and closing the inhaler.

Study burden and risks

The burden of this study pertains to one additional visit for instructions and three additional visits to the hospital to assess the lung function by spirometry. Furthermore, a ACQ and AQLQ questionnaire needs to be filled in at the start of phase 1 and at the end of each phase. The potential benefit of this study is that by improving therapy adherence and inhalation technique, asthma control may be improved.

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

- Patients from 18 years or older.
- Patients who suffer from difficult to treat asthma.
- Patients are under treatment in MST

Exclusion criteria

- Patients who are unable to speak or understand the Dutch language.
- Current smokers
- Patients who are not compatible with the medication delivered through the Nexthaler, Ellipta or Spiromax. Switch between dosis aerosol and dry powder inhaler device is allowed if the medication remains the same. Patients should use this device at least a month before entering the study.
- Patients with a chronic disease other than asthma that can influence the lung function.
- Patients who use a biological drug for their asthma

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	68
Type:	Anticipated

Medical products/devices used

Generic name:	Respiro add-on
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-02-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	10-05-2022
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	NL71910.100.19