Monitoring of exhaled nitric oxide (FENO) to tailor the lowest effective dose of oral corticosteroids in severe asthma

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To reduce the consumption of oral corticosteroids (OCS) in patients with severe asthma while maintaining asthma control, in order to decrease the incidence of long-term steroid-induced side effects and to improve quality of life (QoL). The specific...

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

Summary

ID

NL-OMON30375

Source
ToetsingOnline

Brief title
MONOSA-study

Condition

- Bronchial disorders (excl neoplasms)

Synonym
severe asthma, steroid-dependent asthma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: dossiernr 80-007029-98-07015,Aerocrine, Solna, Zweden (producent van stikstofoxide meter)

Intervention

Keyword: asthma, nitric_oxide

Outcome measures

Primary outcome

Cumulative dose of oral corticosteroids, symptoms (ACQ), quality of life

(AQLQ), patient's health state (VAS).

Secondary outcome

EQ-5D, SF-12, lung function, exacerbations, emergency visits, hospitalisations,

steroid side effects

Study description

Background summary

The goal of therapy in patients with severe asthma is to achieve the best possible result on symptoms and lung function, and the least adverse effects from medication. Measurements of the fraction of exhaled nitric oxide (FENO) constitute a non-invasive marker of airway inflammation that has been successfully used to adjust the dose of inhaled corticosteroids in mild-to-moderate asthma in adults. A pilot study performed at the Leiden University Medical Center in severe asthmatic adults using 10-130 mg oral prednisone daily, showed that FENO could be used to safely reduce and ultimately discontinue OCS This suggests that FENO is an appropriate tool that can be used to tailor the lowest effective dose of OCS in patients with severe asthma while maintaining asthma control and improving quality of life.

Study objective

To reduce the consumption of oral corticosteroids (OCS) in patients with severe asthma while maintaining asthma control, in order to decrease the incidence of long-term steroid-induced side effects and to improve quality of life (QoL).
The specific research questions are:
1. Does monitoring of exhaled nitric oxide (FENO) in severe asthma facilitate tapering of OCS to the lowest effective dose, leading to a reduction of corticosteroid consumption?
2. Can this be achieved without worsening of asthma control or asthma-related

QoL (AQLQ)?

Study design

A prospective, randomised, parallel, multicenter trial. Randomisation in 2 strategies: dose adjustments of oral corticosteroids (OCS) according to usual care on a monthly basis or guided by FENO (FENO strategy). All patients record symptoms and lung function daily, and complete asthma control questionnaires (ACQ) weekly. Patients in the FENO strategy group also measure FENO daily at home. Data are transferred via an asthma monitoring service using SMS messages or Internet. Patients in the FENO group receive instructions to adjust the dose of OCS electronically on a weekly basis. Both groups are followed for 6 months.

Intervention

see Study design

Study burden and risks

The burden for the patient is:
Daily monitoring of symptoms, medication use and measurement of lung function by a handeheld electronic spirometer (10 minutes). Weekly completion of asthma control questionnaire (10 minute). Transfer of data via SMS or internet to a central computer.

2. Monthly visits to the pulmonologist (15 minutes appointment)

3. three-monthly completion of 3 questionnaires (15 minutes)

The health risk for the patient by this intervention is not increased, it is probably decreased.

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

- 18-65 years
- pulmonologist's diagnosis of severe asthma
- daily or alternate day oral corticosteroid therapy for at least 1 month before entering into the study
- maintenance high dose inhaled corticosteroids (at least 1600 mcg/day beclomethasone equivalent) and long- and short acting bronchodilators for more than one year

Exclusion criteria

- The patient is not able to perform adequate measurements of FENO at home
- The patient has no mobile phone or internet access

Study design

Design

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

Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2007
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL14613.058.06