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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19976

Source
NTR

Brief title
MONOSA

Health condition

1. Severe asthma;

2. corticosteroids;

3. adverse effects;

4. nitric oxide.

(NLD: Ernstig astma, corticosteroid, bijwerkingen, stikstofoxide).

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam University;
Medical Center Leeuwarden ;
Haga Ziekenhuis den Haag;

Medisch Spectrum Twente;
Leiden University Medical Center
Source(s) of monetary or material Support: ZonMw
Aerocrine AB

Intervention

Outcome measures

Primary outcome

1. Cumulative dose of OCS;

2. symptoms (ACQ);

3. quality of life (AQLQ);

4. patient's health state (VAS).

Secondary outcome

1. EQ-5D;

2. SF-12;

3. lung function;

4. exacerbations;

5. emergency visits;

6. hospitalisations;

7. steroid side effects.

Study description

Background summary

Patients with steroid dependent asthma have continued morbidity from both their disease and the systemic steroid (OCS) that they are using. Specialists try to adjust their OCS dose based on symptoms and signs, without the use of a specific marker reflecting the activity of the underlying inflammatory process. Our question is whether the exhaled nitric oxide (FENO)

can help in tapering OCS in patients with severe asthma while maintaining asthma control, in order to decrease the incidence of serious side effects and to improve quality of life (QoL).

Measurements of the fraction of exhaled nitric oxide 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. We postulate that a FENO-based strategy for steroid-dose adjustment could help to reduce the cumulative steroid dose and improve quality of life in patients with severe asthma.

Therefore 100 adults with steroid dependent asthma will be randomised in 2 strategies: dose adjustments of 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.

Study objective

1. Daily home monitoring of exhaled nitric oxide (FENO) in patients with severe asthma facilitate tapering of oral corticosteroids to the lowest possible dose, leading to a reduction of total corticosteroid consumption;

2. This can be achieved without a deleterious effect on asthma control and disease-associated quality of life.

Study design

N/A

Intervention

Patients are randomised 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.
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Contacts

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Eligibility criteria

Inclusion criteria

1. 18-65 years;

2. Pulmonologysts' diagnosis of severe asthma;

3. Daily or alternate day oral corticosteroid therapy for at least 1 month before entering into the study;

4. 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

1. Patient not able to perform adequate measurements of FENO at home;

2. Patient without mobile phone or internet access.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2007
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion

Date:	28-11-2007
Application type:	First submission

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
NTR-new	NL1111
NTR-old	NTR1146
Other	: incomplete
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A