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

Gepubliceerd: 28-11-2007 Laatst bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19976

Bron
NTR

Verkorte titel
MONOSA

Aandoening

1. Severe asthma;

2. corticosteroids;

3. adverse effects;

4. nitric oxide.

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

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam University;
Medical Center Leeuwarden ;
Haga Ziekenhuis den Haag;
Medisch Spectrum Twente;
Leiden University Medical Center
Overige ondersteuning: ZonMw
Aerocrine AB

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Cumulative dose of OCS;
2. symptoms (ACQ);
3. quality of life (AQLQ);
4. patient's health state (VAS).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.
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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

2. Patient without mobile phone or internet access.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2007

Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	28-11-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1111
NTR-old	NTR1146
Ander register	: incomplete
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A