Difficult to treat asthma at high altitude

Gepubliceerd: 14-04-2008 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON26574

Bron
NTR

Verkorte titel
Difficult to treat asthma at high altitude

Aandoening

Difficult to treat asthma
Phenotypes of severe asthma
Clinical features
Pathophysiology
High altitude treatment

Moeilijk te behandelen astma
Fenotypen van ernstig astma
Klinische kenmerken
Pathofysiologie
Hooggebergte behandeling

Ondersteuning

Primaire sponsor: Vereniging Nederland Davos

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Improvement in Asthma-control (ACQ) and FEV1 and decrease in mean oral steroid maintenance dose.

Toelichting onderzoek

Achtergrond van het onderzoek

Background: Patients with difficult-to treat asthma remain symptomatic despite the use of high doses of currently available medication. They have greater morbidity,and poorer quality of life than patients with milder forms of the disease, and consume a disproportionate amount of healthcare resources for asthma. Patients with difficult-to-treat asthma form a heterogeneous group, and phenotyping is necessary in order to increase our understanding of the disease and develop novel treatments. Interesting, a proportion of patients with difficult-to-treat asthma seem to improve during treatment at high altitude. However the characteristics of these patients and the mechanisms by which they improve are still largely unknown.

Objective of the study:

1. Can difficult-to-treat asthma be divided in different phenotypes with different responses to high altitude treatment?

2. Are there specific markers or clinical characteristics in patients with difficult-to-treat asthma that predict the short term and longterm effect of high altitude treatment?

3. Is the response to high altitude treatment associated with changes in the level of activated vitamin D?

Study design:

In this longitudinal, prospective, 15 months follow up study, the patients will be assessed at entry and after 6 and 12 weeks of a standard rehabilitation programme at high altitude in the Dutch Asthmacentre Davos, and thereafter at discharge, and dutring 12 months at sea level at 3-monthly intervals.

Onderzoeksopzet

15 months follow up study

Patients will be assessed at entry and after 6 and 12 weeks of a standard rehabilitation programme at high altitude in the Dutch Asthmacentre Davos, and thereafter at discharge, and dutring 12 months at sea level at 3-monthly intervals.

Onderzoeksproduct en/of interventie

Integrated multidisciplinary assesment of the asthma-control status, asthma history, asthma specific health status,
co-morbidity, asthma- triggering factors, medication need, lungfunction,
inflammation markers and excercise tolerance.

The pulmonary rehabilitation, according to ERS guidelines, will be adjusted to this integrated assessed profile of the patient in the allergen and pollutionfree high altitude climate in Davos with low relative humidity during 12 weeks.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 18-80 year

2. Difficult to treat asthma, defined as uncontrolled asthma despite the chronic use of > 1600 mcg inhaled beclomethason equivalent plus longacting beta-2 agonists or oral steroids.

3. Smoking history < 15 years, or reversibility in FEV1 to short acting beta agonist > 9%.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion for treatment in Davos:

1. Active cardio-vascular disease

2. Active and acute psychiatric disease in need of treatment by a psychiatrist.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2007
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-04-2008
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	NL1232
NTR-old	NTR1277
Ander register	MEC : 07/206
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

- Bel, E. H. 2004. Clinical phenotypes of asthma. Curr.Opin.Pulm.Med. 10:44-50.
- Rijssenbeek-Nouwens LH, Bron AO, Naves C, Weller F, Weersink EJ, and Bel EH. Persistent airflow limitation in severe asthma is not an irreversible phenomenon. Proceedings of the American Thoracic Society 3 (abstract issue), A580. 2006.
- Grootendorst, D. C., S. E. Dahlen, J. W. Van Den Bos, E. J. Duiverman, M. Veselic-Charvat, E. J. Vrijlandt, S. O'Sullivan, M. Kumlin, P. J. Sterk, and A. C. Roldaan. 2001. Benefits of high altitude allergen avoidance in atopic adolescents with moderate to severe asthma, over and above treatment with high dose inhaled steroids. Clin.Exp.Allergy. 31:400-408.