Difficult to treat asthma at high altitude

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26574

Source
NTR

Brief title
Difficult to treat asthma at high altitude

Health condition

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

Sponsors and support

Primary sponsor: Vereniging Nederland Davos

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Improvement in Asthma related Quality of Life (AQLQ), rhinosinusitis score (RSOM-31) fatique score (CIS-Fatique), body mass index (BMI), residual volume as percentage of total lung capacity (RV/TLC), exhaled nitric oxide (FeNO), changes in levels of 25-hydroxyvitamin D and 1.25-(OH)2 vitamin D.

Study description

Background summary

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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%.

Exclusion criteria

Exclusion for treatment in Davos:

1. Active cardio-vascular disease

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

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2007
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-04-2008
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	NL1232
NTR-old	NTR1277
Other	MEC : 07/206
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

- 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.