High-altitude treatment versus treatment at sea level in patients with severe, refractory asthma: a pragmatic randomized clinical trial

Gepubliceerd: 29-05-2015 Laatst bijgewerkt: 15-05-2024

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Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23233

Bron
NTR

Aandoening

severe refractory asthma; high altitude treatment; multidisciplinary rehabilitation

Ondersteuning

Primaire sponsor: Merem Behandelcentra
Overige ondersteuning: Merem Behandelcentra,
pending requests for additional funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Asthma-specific Quality of Life assessed with the The 32-item Asthma Quality of Life Questionnaire

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: In the recent guideline
Diagnostiek en behandeling van ernstig astma" pulmonary rehabilitation at high altitude is considered a treatment option for adult patients with severe asthma and insufficient symptom control despite optimal medical treatment. High altitude treatment combines asthma treatment with exposure to a trigger poor environment. Part of the high altitude treatment effect is attributed to changes in environmental triggers (low humidity air, lower general air pollution, absence of house dust mite allergen exposure and lower microbial exposure). The Dutch asthma centre in Davos (CH) at an altitude of 1650 metres is a tertiary asthma centre offering rehabilitation treatment to patients with severe asthma. Despite a long history of high altitude treatment in severe asthma, its relative short and long-term effectiveness compared to sea level treatment is unknown due to a lack of high-quality controlled studies. The Dutch Health Insurance Board (Zorginstituut Nederland) has commissioned a comparative study to investigate the short and long-term effectiveness of high-altitude pulmonary rehabilitation compared with rehabilitation at sea level in patients with severe, refractory asthma.

Objectives: the primary objectives are twofold: 1) to compare the effect of 12 weeks of multidisciplinary pulmonary rehabilitation in a high-altitude centre with comparable rehabilitation in sea level centre(s) on asthma-specific quality of life (assessed with the Asthma Quality of Life Questionnaire, AQLQ) in patients with severe, refractory asthma; and 2) to compare the AQLQ values over a one-year period in subjects who received 12 weeks of multidisciplinary pulmonary rehabilitation in high-altitude versus rehabilitation in sea level centre, adjusting for differences in exposure to environmental triggers, both outdoor and indoor. Environmental exposure will also be monitored in both the high-altitude centre and sea level centre(s).

Study design: a parallel, multicentre, pragmatic, clinical trial with randomized allocation to high-altitude or sea level multidisciplinary pulmonary rehabilitation in combination with environmental allergen and microbial measurements in the home environment.

Study population: Adult subjects with asthma, requiring treatment with guideline suggested medications for GINA steps 4 – 5 asthma (receiving inhaled CS (≥500 µg fluticasone or equivalent) and LABA as maintenance therapy) for the previous year or systemic CS ≥6 months / year, that remain ‘‘uncontrolled’’ despite this therapy, for which multidisciplinary pulmonary rehabilitation in a tertiary lung centre is indicated.
Uncontrolled asthma is defined by the presence of at least one of the following criteria:
1) poor symptom control: ACQ consistently >1.5, ACT <20 (or ‘‘not well controlled’’ by NAEPP

/ GINA guidelines)
2) frequent severe exacerbations: two or more bursts of systemic CS (>3 days each) in the previous year
3) serious exacerbations: at least one hospitalisation, ICU stay or mechanical ventilation in the previous year
4) airflow limitation: after appropriate bronchodilator withhold postbronchodilator FEV1 <80% of predicted (in the face of a reduced FEV1 / FVC, defined as FEV1 / FVC z-score <1.64).
Additional inclusion criteria are:
1) age ≥18 and <75 years
2) inhaler technique is optimized
3) adherence to asthma medication is optimized
4) environmental control measures to limit exposure to allergens are taken
5) optimal treatment of comorbidity
6) no medication which can aggravate asthma
7) patient is a non-smoker or stopped smoking at least 6 months before study entry
8) patient has been treated by a pulmonologist in the past 6 months

Intervention: 12 weeks of intensive pulmonary multidisciplinary rehabilitation either in the high altitude centre in Davos or in a lung centre in The Netherlands. In both centres, the rehabilitation programme is personalized by using a modular approach with standardized treatment modules according to the DBC ¡°Complex longfalen (longrevalidatie)¡±. Environmental measurements are taken according to existing WHO protocols (house dust) or newly developed low tech approaches and existing monitoring networks in Switzerland and the Netherlands (PM10 and NOx).

Main study parameter: asthma-specific quality of life assessed with the Asthma Quality of life questionnaire.

Doel van het onderzoek

It is hypothesized that 12 weeks of multidisciplinary pulmonary rehabilitation in a high-altitude centre (in Davos) is superior to a comparable rehabilitation programme in sea level centre (in The Netherlands) in improving asthma-specific quality of life of patients with severe, refractory asthma.

Onderzoeksopzet

Baseline (T0, prior to treatment), every 3weeks during treatment, end of treatment and every three months during 1 year follow up

Onderzoeksproduct en/of interventie

Treatment consists of an intensive pulmonary multidisciplinary rehabilitation program either in the high altitude asthma centre in Davos or in a tertiary lung centre (Heideheuvel) in The Netherlands.

The high altitude clinic Dutch Asthma Centre Davos and the asthma clinic Heideheuvel in The Netherlands (LCN) supply structured, quality-controlled, comprehensive personalized treatment for adults with severe asthma, which includes attempts to achieve full asthma control and to reduce (oral) corticosteroids to the lowest effective level, exercise training, asthma education and self-management and psychological support. Treatment is personalized by using a modular approach with standardized treatment modules according to the DBC ¡¡ãComplex longfalen (long-revalidatie)¡¡À. This DBC consist of 9 basic modules (Medication and inhalation; exacerbation; self-management; physical fitness; daily physical activity; functional-ADL-training, dyspnoea management; food and diet; coping; problems in family interactions) which all patients receive and 24 additional modules for which specific inclusion criteria are described in the DBC.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult subjects with asthma, requiring treatment with guideline suggested medications for GINA steps 4 – 5 asthma (receiving inhaled CS (≥500 µg fluticasone or equivalent) and LABA

as maintenance therapy) for the previous year or systemic CS ≥6 months / year, that remain ‘‘uncontrolled’’ despite this therapy, for which multidisciplinary pulmonary rehabilitation in a tertiary lung centre is indicated.
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Additional inclusion criteria are:

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3) adherence to asthma medication is optimized

4) environmental control measures to limit exposure to allergens are taken

5) optimal treatment of comorbidity

6) no medication which can aggravate asthma

7) patient is a non-smoker or stopped smoking at least 6 months before study entry

8) patient has been treated by a pulmonologist in the past 6 months

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study if he / she:

1)participated in a clinical trial in the preceding three months

2)has known alcohol abuse or a severe unstable psychiatric condition requiring treatment

3)has unstable cardiovascular status

4)is pregnant or planning to become pregnant;

5)suffers from other lung disease that impact on asthma symptoms

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2015
Aantal proefpersonen:	160
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47209
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5044
NTR-old	NTR5182
CCMO	NL53835.018.15
OMON	NL-OMON47209

Resultaten