Prevention of asthma exacerbations by the regular use of a bacterial lysate (Broncho-Vaxom).

Gepubliceerd: 25-08-2016 Laatst bijgewerkt: 15-05-2024

Primary: The number and duration of asthma exacerbations will diminish with the regular use of a bacterial lysate. Secondary: -Regular bacterial lysate treatment improves health (pulmonary function, quality of life, medication use). - Respiratory-...

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

Samenvatting

ID

NL-OMON28868

Bron
NTR

Verkorte titel
Breathe-study

Aandoening

asthma, respiratory tract infections, bacterial lysates, inflammation

Ondersteuning

Primaire sponsor: Investigator initiated trial by clinical researchers of the Department of Pediatrics and Department of Pulmonology; Franciscus Gasthuis & Vlietland, Rotterdam
Overige ondersteuning: initiator = sponsor
Other:
- European Society for Pediatric Infectious Diseases (ESPID)
- Coolsingel foundation Rotterdam
- Vifor Pharma (requested by the PI)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Total number of asthma exacerbations within 18 months after initiation of intervention.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Bacterial lysates can modulate the immune system by effects on T-cells (skewing to the Th1-type by Treg cells) and on the inflammatory response to microorganisms. There is evidence for a reduction of infectious- and asthmatic symptoms in young children after using bacterial lysates. Yet, the effect of bacterial lysates on reduction of asthma severity and inflammatory parameters in adolescents and adults with moderate to severe asthma has not yet been studied. However, they might well benefit well from reduction of respiratory infections and attenuation of Th2-related inflammation. Therefore, we want to initiate a clinical- and laboratory study into the effects of regular treatment with bacterial lysates in adolescents and adults with proven asthma.
Main objective: To diminish the number and duration of asthma exacerbations with the regular use of a bacterial lysate.
Study design: Investigator-initiated double-blind randomized controlled trial.
Study population: Patients aged 12-60 years with proven asthma (airway responsiveness proven by reversibility and histamine PC20 < 8 mg/ml)) who have recurrent airway signs and symptoms despite optimal maintenance medication (medium/high dose inhalation corticosteroid and long-acting B2-agonist; GINA 4) and >= 2 exacerbations in the previous year.
Intervention (if applicable): Bacterial lysate OM-85 (Broncho-Vaxom, OM Pharma) 7 mg capsules versus identical placebo capsules; given in the first consecutive 10 days of each month (October-March (6 months/year)), during 2 years.
Main study parameters/endpoints: Number of astma exacerbations within 18 months after initiation of intervention.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Broncho-Vaxom is a bacterial lysate that has been used for years in children and adults with recurrent respiratory tract infections. However, for study purposes, it is hardly studied in asthmatic individuals, till now only in young children. In older subjects with COPD, bacterial lysates seem to have a positive effect on lung health. We want to investigate whether this observed positive effect on lung health could also be observed in adolescent and adult asthmatic patients.

Doel van het onderzoek

Primary:
The number and duration of asthma exacerbations will diminish with the regular use of a bacterial lysate.

Secondary:
-Regular bacterial lysate treatment improves health (pulmonary function, quality of life, medication use).
- Respiratory- and gut microbial colonization dynamics change with the regular use of a bacterial lysate
-Airway- and blood immunological markers (T-cell dynamics; cytokine production, ILC2-activity) will change with the regular use of a bacterial lysate.

Onderzoeksopzet

Primary outcome: T= 18 months.
Other outcomes: T=18 and T=30 months

Onderzoeksproduct en/of interventie

Bacterial lysate OM-85 (Broncho-Vaxom, OM Pharma) 7 mg capsules versus identical placebo capsules; given in the first consecutive 10 days of each month (October-March (6 months/year)), during 2 years.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Subjects aged 12-60 years with proven asthma (airway responsiveness proven by reversibility or histamine PC20 < 8 mg/ml)) who have recurrent airway signs and symptoms despite optimal maintenance medication (medium/high dose inhalation corticosteroid and long-acting ¦Â2-agonist; GINA 4).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-Other relevant respiratory conditions, e.g. OSAS, bronchiectasis
-Systemic immunological diseases/systemic immunosuppression
-Current smoking or past smoking > 10 pack years
-Other untreated co-morbidity, such as gastro-esophageal reflux disease, ENT problems, psychological disorders
-Non-compliance to current medication or inhalation technique
-Communication difficulties
-Pregnancy or planned pregnancy within 2 years

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2016
Aantal proefpersonen:	75
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	25-08-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43072
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5752
NTR-old	NTR6018
CCMO	NL57294.101.16
OMON	NL-OMON43072

Resultaten

Samenvatting resultaten
to follow