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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28868

Source
Nationaal Trial Register

Brief title
Breathe-study

Health condition

asthma, respiratory tract infections, bacterial lysates, inflammation

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

-Number of suspected infectious asthma exacerbations (asthma exacerbation + symptoms of respiratory tract infection + proven new respiratory viral or bacterial pathogen)
-Duration of asthma exacerbations
-Time to first asthma exacerbation
-Time between first and second asthma exacerbation
-Number of asthma exacerbations within 3, 6, 12 months after initiation of intervention
-Number of respiratory tract infections
-Change in viral and bacterial colonization
-Days free from asthma symptoms
-Change in pulmonary function (spirometry parameters) from baseline
-Use of oral corticosteroids, B2-agonist treatment and antibiotics
-Change in sputum- and blood inflammatory markers (cytokines, chemokines, lymfocyte populations)
-Change in airway & gut microbiome
-Asthma Quality of life/Asthma control questionairre
-Number of outpatient doctor's visits and hospitalisation
-Number of adverse and serious adverse events

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

-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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2016
Enrollment:	75
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-08-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43072
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
to follow