ISRCTN25212012 https://doi.org/10.1186/ISRCTN25212012

Evaluation of Broncho-Vaxom(R) ability to respond to the induction of inflammation through the inhalation of a bacterial component

Submission date 18/09/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 24/10/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 24/10/2012	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BV2012/05

Study information

Scientific Title
Clinical and immune modifying capacity of Broncho-Vaxom tested by LPS challenge in healthy volunteers

Study objectives
To demonstrate that healthy volunteers treated with Broncho-Vaxom (BV) will develop total antibody levels (i.e. total secretory IgA in saliva) after 4 weeks of treatment compared to placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the State Medical Association Hesse, 27 August 2012, ref: FF61/2012

Study design
Randomized double-blind placebo-controlled single center phase II trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Bronchitis

Interventions
Skin prick test, blood sampling, at visit 4, all subjects will inhale a single dose of 50ug Escherichia coli - Lipopolysaccharide via a medic aid nebulizer and an aerosol provocation system powered by compressed air, ECG and spirometry

Intervention Type
Other

Phase
Phase II

Primary outcome measure
The change from baseline on total IgA level in saliva after 4 weeks of treatment

Secondary outcome measures
1. The reduction of the inflammatory response after a LPS inhalation challenge
2. The reduction on one of the following LPS-induced responses:
2.1. Leukocytes, neutrophils, CRP, LPS-binding protein (LBP) levels in serum
2.2. Neutrophilic inflammation and inflammatory cytokines in induced sputum
2.3. Bronchoconstriction (FEV1 decrease)
2.4. Local symptoms: cough, chest tightness
2.5. Systemic effects like increase of body temperature, chills and headache

Overall study start date
29/08/2012

Completion date
31/01/2013

Eligibility

Key inclusion criteria
1. Patients who have been informed of the study procedures and medications and have given their written informed consent
2. Healthy male and female of any race
3. Aged 18 to 45 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Have received systemic or inhaled corticosteroids within 4 weeks before Visit 1
2. Have smoked on a regular basis within 2 years before Visit 1 or who have a smoking history > 10 pack years
3. An active lung disease (e.g. asthma, chronic bronchitis, COPD)
4. Have suffered from a respiratory tract infection within 4 weeks preceding the study period.
5. Predicted FEV1 below 80% at visit 1
6. Clinically significant uncontrolled systemic disease or a history of such disease (e.g. cancer, infection, hematological disease, renal, hepatic, coronary heart disease or other cardiovascular

disease, endocrinology or gastrointestinal disease) within the previous 3 months
7. Clinically significant laboratory abnormalities at Visit 1
8. A platelet count less or equal to 130 x 10@9/L at Visit 1
9. A result for Methacholine-test below 0.1 mg at Visit 1
10. Skin prick test result >5mm and a corresponding history of allergic asthma
11. With a clinically significant abnormal finding detected on Electrocardiogram at visit 1
12. A history of food or drug related severe anaphylactoid or anaphylactic reaction(s)
13. Are pregnant or nursing mothers
14. Who are of child bearing potential and who are not protected by a reliable contraceptive method (oral, subcutaneous, mechanical, or surgical contraception). Any woman who becomes pregnant during the course of the study must be discontinued, any female who starts her menarche during the trial and is not, for whatever reason, protected by a medically approved contraception must be withdrawn from the trial
15. Known hypersensitivity to any ingredients of BV
16. Volunteers who are considered potentially unreliable and volunteers who may not reliably attend study drug visits
17. A history of drug or alcohol abuse
18. Are unable to perform spirometry and peak flow measurements or complete the subject's diary
19. Have participated in another clinical study within 3 months prior to Visit 1

Date of first enrolment
29/08/2012

Date of final enrolment
31/01/2013

Locations

Countries of recruitment
Germany

Study participating centre
Zentrum für Kinder- und Jugendmedizin
Frankfurt/Main
Germany
60590

Sponsor information

Organisation
OM Pharma [Vifor Pharma] (Switzerland)

Sponsor details
c/o Christian Terreaux
Rue du Bois du Lan 22

Meyrin/Geneva
Switzerland
CH-1217

Sponsor type
Industry

Website
http://www.viforpharma.com/en/

ROR
https://ror.org/0185z7g17

Funder(s)

Funder type
Industry

Funder Name
OM Pharma [Vifor Pharma] (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration