

Efficacy and tolerability of Alviolife™ in the treatment of bronchial asthma

Submission date 29/04/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 26/03/2010	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 15/04/2010	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

Contact name
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Contact details
Department of Pulmonary Medicine
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534004

Additional identifiers

Protocol serial number
09-001/Resp/As

Study information

Scientific Title
Efficacy and tolerability of Alviolife™ in the treatment of bronchial asthma: a randomised, double-blind placebo controlled clinical study

Study objectives

Alviolife™ is a novel herbal composition. In vitro human monocyte/macrophage cell-based assays demonstrate that Alviolife™ inhibits pro-inflammatory cytokine tumour necrosis factor-alpha (TNF-alpha) and adipocyte/macrophage fatty acid-binding protein aP2 (aP2), a protein which regulates allergic airway inflammation. In addition, Alviolife™ attenuates the TH1/TH2 cytokine imbalance in sephadex induced airway inflammation model of Sprague Dawley rats.

Therefore, we hypothesise that this novel herbal composition, Alviolife™ can be used as a therapeutic agent in treating human airway inflammatory diseases like asthma.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board (IRB) of Alluri Sitarama Raju Academy of Medical Sciences (ASRAM) approved on the 2nd February 2009 (ref: # ASRAM IRB # 09-001/Resp/As)

Primary study design

Interventional

Study design

Randomised double blind placebo controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bronchial asthma

Interventions

60 subjects randomised into 3 groups (n = 20):

Test Product 1: Alviolife™ 150 mg (75 mg twice daily [bid])

Test Product 2: Alviolife™ 250 mg (125 mg bid)

Test Product 3: Placebo (suitable excipients [yellow dextrin])

Total duration of interventions is 56 days, follow-up evaluations at baseline, day 7, 14, 28 and 56.

Contact details for patient information material:

Laila Impex R&D Centre

Unit-1, Phase-III

Jawahar Autonagar

Vijayawada 520 007

India

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Alviolife™

Primary outcome(s)

Measured at baseline, day 7, 14, 28 and 56:

1. Symptom score
2. Asthma quality of life questionnaire score
3. Daytime and nocturnal score
4. Symptom free days
5. Rescue medication free days
6. Number of rescue medications inhaled (number of occasions)
7. Adverse events
8. Clinical laboratory abnormalities

Key secondary outcome(s)

Mean percent change from baseline to endpoint in:

1. Peak expiratory flow (PEF) values
2. FEV1
3. Other serum biomarker indices such as TNFalpha, IL-4, IFNgamma

Completion date

30/01/2010

Eligibility**Key inclusion criteria**

1. Participants must understand the risks and benefits of the protocol
2. Age range of 21 - 60 years having moderate to severe bronchial asthma (male or female, with a diagnosis of asthma for at least one year)
3. Observed symptoms of bronchial asthma (dyspnoea, wheezing, tightness in chest, cough etc.)
4. Subjects with mild to moderate obstruction on PFT with significant bronchio-reversibility
5. Subjects with severe asthma with significant bronchio-reversibility and clinically stable
6. Chest radiograph without evidence of pulmonary disease, other than asthma
7. Forced expiratory volume in 1 second (FEV1) had to be greater than 70% of the predicted value (after withholding β agonist for greater than 6 hours) at the pre-study visit and to improve by greater than 15% (absolute value) after inhaled β agonist
8. Ability to provide informed consent, as evidenced by signing a copy of the consent form approved by the Institutional Review Board
9. Moderate asthma is defined as follows (summarised from the National Asthma Education Program Expert Panel Report, USPHS Publication No. 91-304, p. 71-86): moderate asthma is characterised by symptoms poorly regulated by episodic administration of a β_2 agonist. Included in this category is asthma causing frequent symptomatic exacerbations (more than twice a week, at night, or with ordinary activities).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Severe bronchial asthma (peak expiratory flow rate [PEFR] less than 20% and forced expiratory volume in 1 second (FEV1) less than 20% of predicted value)
2. Pregnant and lactating women, subjects having chronic bronchitis and/or emphysema, or subjects suffering from concurrent systemic diseases, with cardiopulmonary tuberculosis, pulmonary eosinophilia, bronchiectasis, cancer, cardiovascular disorders or breathlessness due to cardiovascular disorders, hepatic dysfunction, neurological disorders and diarrhoeal disorders
3. Respiratory tract infection and other serious medical illnesses in addition to asthma
4. History of lung disease other than asthma (i.e., chronic obstructive pulmonary disease [COPD], sarcoidosis)
5. History of diabetes mellitus, insulin secreting tumour, or symptomatic hypoglycaemia
6. Human immunodeficiency virus (HIV) or other known immunodeficiency
7. Pre-existing oedema (2-plus or greater)
8. Haemoglobin less than 12 g/dl for males and less than 11 g/dl for females
9. History of liver disease or abnormal liver function tests greater than 2 x upper limit of normal
10. History of drug or alcohol abuse
11. Subjects must be non-smokers of cigarettes, pipes or cigars

Date of first enrolment

12/02/2009

Date of final enrolment

30/01/2010

Locations**Countries of recruitment**

India

Study participating centre

Department of Pulmonary Medicine

Eluru

India

534004

Sponsor information**Organisation**

Laila Impex R&D Center (India)

ROR

<https://ror.org/05q6g7072>

Funder(s)

Funder type

Industry

Funder Name

Laila Impex R&D Center (India)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration