

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

<b>Submission date</b> 29/04/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/03/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/04/2010	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Pothina Yugandhar

**Contact details**  
Department of Pulmonary Medicine  
Alluri Sitarama Raju Academy of Medical Sciences (ASRAM)  
Eluru  
India  
534004

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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)

### **Study design**

Randomised double blind placebo controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use the details found in the interventions section to request a patient information sheet

### **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 measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

12/02/2009

### **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  $\beta$  agonist for greater than 6 hours) at the pre-study visit and to improve by greater than 15% (absolute value) after inhaled  $\beta$  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  $\beta_2$  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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

60

**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)

**Sponsor details**  
Unit 1, Phase III  
Jawahar Autonagar  
Vijayawada  
India  
520 007

**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://lailaimpex.tradeindia.com>

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

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Laila Impex R&D Center (India)

## 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