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

Submission date	Recruitment status	[ ] Prospectively registered
29/04/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/03/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/04/2010	Respiratory	[ ] 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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Department of Pulmonary Medicine
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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 mococyte/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 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 ß agonist for greater than 6 hours) at the pre-study visit and to improve by greater than 15% (absolute value) after inhaled ß 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 ß2 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