

# Efficacy of three nutraceutical products of herbal origin in weight management of obese human subjects: a randomised, double blind, placebo controlled clinical study

**Submission date**

14/11/2007

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

22/11/2007

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

28/09/2012

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Artatrana Mishra

**Contact details**

Department of General Medicine

ASR Academy of Medical Sciences

Eluru

India

534 002

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**

07/001/PHF Ob

# Study information

## Scientific Title

### Acronym

Anti-obese Nutraceuticals

### Study objectives

Public Title: Clinical efficacy of three nutraceutical products of herbal origin in obese subjects

Supplementation of three natural polyherbal formulations will be helpful for management of weight control in obese human subjects.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received from the Internal Review Board of ASR Academy of Medical Sciences (India) on the 5th October 2007 (ref: 07-01/IB/PHF Ob).

### Study design

This is a randomised, double blind, placebo-controlled study

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Treatment

### Participant information sheet

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

Obesity

### Interventions

A total of 100 human subjects is randomised and divided into four groups:

1. Adipolean
2. Adipolite
3. Betelean
4. Placebo

The treatment dosage is 1500 mg day, consisting of three 500 mg doses daily for the active treatment groups. Each subject in the fourth group will receive color matched equal amount of placebo per day.

The study duration will be 56 days. The visits and the evaluations will be at the baseline, 14th day, 28th day, and the 56th day.

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Adipolean, Adipolite, Betelean

### **Primary outcome measure**

1. Physical/anthropometric parameters:

1.1. Body weight

1.2. Body mass Index

1.3. Waist hip ratio

2. Biochemical parameters (serum/plasma):

2.1. Fasting glucose

2.2. Fasting insulin

2.3. Triglyceride

2.4. Cholesterol

2.5. High Density Lipoprotein (HDL) cholesterol

2.6. Low Density Lipoprotein (LDL) cholesterol

The primary and secondary outcomes will be measured on baseline, 14th day, 28th day and 56th day.

### **Secondary outcome measures**

Obesity biomarkers (serum/plasma):

1. Leptin

2. Glucagon like peptide-1

3. Adiponectin

4. Ghrelin

The primary and secondary outcomes will be measured on baseline, 14th day, 28th day and 56th day.

### **Overall study start date**

15/11/2007

### **Completion date**

20/01/2008

## **Eligibility**

### **Key inclusion criteria**

1. Adults aged 21 - 50 years
2. Body Mass Index (BMI) greater than or equal to 30 kg/m<sup>2</sup>
3. Willingness to participate in an exercise-walking program, supervised by a trained exercise specialist
4. Willingness to consume the prescribed study diet of approximately 2,000 KCal per day as outlined in the protocol (meals will be provided at free of cost by the study sponsor)
5. Written informed consent to participate in the trial
6. Willingness to complete standard health history questionnaire before induction into the study
7. Willingness to participate in five clinic visits (screening, baseline, 2, 4 & 8 weeks)
8. If female:
  - 8.1. Should be negative in pregnancy test
  - 8.2. If of childbearing potential, should agree to follow an acceptable method of birth control for the duration of the study, such as condoms, foams, jellies, diaphragm, Intrauterine Device (IUD), etc.
  - 8.3. Postmenopausal for at least 1 year
  - 8.4. Surgically sterile (bilateral tubal ligation, bilateral oophorectomy, or hysterectomy)

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

100

**Key exclusion criteria**

1. History of thyroid disease or cardiovascular disease or diabetes
2. Any other clinically significant disorder
3. History of allergy to spices and herbal products
4. Intractable obesity or uncontrolled body weight, BMI greater than 40 kg/m<sup>2</sup>
5. Presently using other weight loss medications, as well as stimulants, laxatives or diuretics taken solely for the purpose of weight loss
6. Recent, unexplained weight loss or gain
7. Positive Human Immunodeficiency Virus (HIV) test
8. History of hepatitis, pancreatitis, lactic acidosis or hepatomegaly with steatosis
9. History of motor weakness or peripheral sensory neuropathy
10. Any evidence of organ dysfunction or any clinically significant deviation from the normal, in physical or clinical determinations

**Date of first enrolment**

15/11/2007

**Date of final enrolment**

20/01/2008

**Locations**

**Countries of recruitment**

India

**Study participating centre**

Department of General Medicine

Eluru

India

534 002

## **Sponsor information**

**Organisation**

Laila Nutraceuticals (India)

**Sponsor details**

Unit-6 & 7

Phase-III

Jawahar Autonagar

Vijayawada

India

520007

**Sponsor type**

Industry

**ROR**

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

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Laila Nutraceuticals (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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	20/09/2012		Yes	No