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Comparative efficacy and tolerability of a novel botanical extract LI 12508 and its formulation LI 12507F in the treatment and control of obesity

Submission date 08/03/2010	**Recruitment status** No longer recruiting
Registration date 30/07/2010	**Overall study status** Completed
Last Edited 20/01/2014	**Condition category** Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
09-006/Ob/Sp

Study information

Scientific Title
Comparative efficacy and tolerability of a novel botanical extract LI 12508 and its formulation LI 12507F in the treatment and control of obesity: a randomised, double-blind placebo controlled clinical study

Acronym
Anti-obese nutraceuticals

Study objectives
Supplementation of herbal formulations might be useful for management of body weight in obese human subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Internal Review Board of ASR Academy of Medical Sciences (India) approved on the 10th February 2010 (Ref: ASRAMIRB 09006)

Study design
Randomised double blind placebo controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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
Obesity

Interventions
A total 60 human subjects will be randomised and divided into three groups:
1. LI-12508
2. LI-12507F
3. Placebo

The treatment dosage is 800 mg daily, consisting of two 400 mg doses daily for the active groups. Each subject included in the third group is receiving matched placebo per day.

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

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
LI 12508, LI 12507F

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. Adiponectin
3. Ghrelin

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

Overall study start date
07/03/2010

Completion date
07/06/2010

Eligibility

Key inclusion criteria
1. Participants must understand the risks and benefits of the study
2. Adults ages 21 - 50 years, either sex

3. Body mass index (BMI) less than 30 kg/m^2
4. Willingness to participate in an exercise-walking program, supervised by a trained exercise specialist
5. Willingness to consume the prescribed study diet of approximately 2,000 K Cal per day as outlined in the protocol (meals will be provided at free of cost by the study sponsor)
6. Ability to provide written informed consent for participation in the trial
7. Willingness to complete standard health history questionnaire before induction into the study
8. Willingness to participate in five clinic visits (Screening, baseline, 2, 4 and 8 weeks)
9. Subject willing to participate in health exercise program (30 minutes walking) monitored by the study physical trainer
10. Subjects must be instructed to abstain from alcoholic products during the study
11. If female, patients:
11.1. Should be negative in pregnancy test
11.2. Should not be nursing
11.3. 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., or post-menopausal for at least 1 year, or surgically sterile (bilateral tubal ligation, bilateral oophorectomy, or hysterectomy)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. History of thyroid disease or cardiovascular disease or diabetes (uncontrolled)
2. Subjects having chronic diarrhoeal disorders, cancer, neurological disorders, hepatic dysfunction
3. Respiratory tract infection and other serious medical respiratory illnesses (i.e., chronic obstructive pulmonary disease [COPD], sarcoidosis)
4. History of allergy to spices and herbal products
5. Intractable obesity or uncontrolled body weight, BMI greater than 40 kg/m^2
6. Non-obese (BMI less than 30 kg/m^2) and morbidly obese (BMI greater than 40 kg/m^2)
7. Presently using other weight loss medications, as well as stimulants, laxatives or diuretics taken solely for the purpose of weight loss
8. Pregnant or nursing or lactating females
9. Recent, unexplained weight loss or gain
10. Women with a positive pregnancy test
11. Human immunodeficiency virus (HIV) or other known immunodeficiency
12. Undergone surgery before 30 days of screening or planning to undergo surgery within the study days
13. History of hepatitis, pancreatitis, lactic acidosis or hepatomegaly with steatosis

14. History of motor weakness or peripheral sensory neuropathy
15. Any evidence of organ dysfunction or any clinically significant deviation from the normal, in physical or clinical determinations

Date of first enrolment
07/03/2010

Date of final enrolment
07/06/2010

Locations

Countries of recruitment
India

Study participating centre
Department of General Medicine
Eluru
India
534002

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?
Results article	results	01/06/2013		Yes	No