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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

Registration date
22/11/2007

Overall study status
Completed

Last Edited
28/09/2012

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
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^2
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^2
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?
Results article	results	20/09/2012		Yes	No