Garcinia Mangostana Extracts in the Management of Weight Loss

This study has been completed.

Sponsor:
University of Roma La Sapienza
Information provided by (Responsible Party):
Carla Lubrano, University of Roma La Sapienza

ClinicalTrials.gov Identifier:
NCT02823561
First received: June 23, 2016
Last updated: August 30, 2016
Last verified: June 2016

History of Changes
- **Full Text View**
- **Tabular View**
- **No Study Results Posted**
- Disclaimer
- How to Read a Study Record

purpose_section

Purpose

Obesity is one of the greatest public health challenges of the 21st century. Its prevalence has tripled in many countries of the European Region since the 1980s, and the numbers of those affected continue to rise at an alarming rate. In addition to causing various physical disabilities and psychological problems, excess weight drastically increases a person's risk of developing a number of noncommunicable diseases including cardiovascular disease, cancer and diabetes, in association or not to metabolic syndrome. The risk of developing more than one of these diseases (co-morbidity) also increases with increasing body weight. Every year a growing number of patient tend to suffer of more severe obesity and difficulty in losing weight even with a restricted diet and exercise.

Garcinia mangostana (Sphaeranthus indicus extract) has known for its antioxidant properties; new evidence point out some promising effects in the prevention of lipogenesis and the promotion of lipolysis . Currently in the scientific literature there is only one paper, by Stern et al., showing the association of **Garcinia mangostana** assumption in low-calorie diet. This work has demonstrated a significant reduction in weight loss , compared to the placebo group,due to the use of **Garcinia mangostana**.

Aim of the present study is the evaluation of safety and efficacy of weight loss in severe obese patients. Also cardiometabolic parameters and flogosys serum indicators will be evaluated before and after 6 month therapy of low calory diet alone or in association with **Garcinia mangostana** extract.

condition, intervention, phase summary table

Condition	Intervention
Severe Obesity	Dietary Supplement: **Garcinia mangostana** Behavioral: Control group

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment
Official Title: Efficacy and Tolerability of **Garcinia Mangostana** Extracts in the Man Patients
NLM links
Resource links provided by NLM:

medline links
MedlinePlus related topics: Body Weight Weight Control
U.S. FDA Resources
more details
Further study details as provided by University of Roma La Sapienza:

primary outcomes
Primary Outcome Measures:
- Weight loss - Kg reduction [Time Frame: 26 weeks]
  [Designated as safety issue: No]

secondary outcomes
Secondary Outcome Measures:
- **Insulin sensitivity assessed by the homeostatic model assessment (HOMA-IR) [Time Frame: 26 weeks]**
  [Designated as safety issue: No]
- **Lipid profile by serum biochemistry [Time Frame: 26 weeks]**
  [Designated as safety issue: No]
- **Abdominal obesity measured by waist circumference [Time Frame: 26 weeks] [Designated as safety issue: No]**
- **Body composition by Dexa parameters [Time Frame: 26 weeks]**
  [Designated as safety issue: No]
- **Changes in microalbuminuria by unin analysis [Time Frame: 26 weeks] [Designated as safety issue: No]**

Enrollment: 40

Study Start Date:	November 2015
Study Completion Date:	May 2016
Primary Completion Date:	May 2016 (Final data collection date for primary outcome measure)

arms and groups table

Arms
Active Comparator: **Garcinia mangostana** (treatment group) Balanced low-calorie diet and regular exercise in combination with integration
Control group balanced low-calorie diet and regular exercise

detailed description **Detailed Description:**
After the screening visit for the evaluation of the inclusion / exclusion criteria and sign informed consent(Visit 1), each patient will be randomized (Visit 2; Time 0; Baseline) (1: 1) to receive two different treatment for the duration of 26 weeks:

1 low-calorie balanced diet consistent exercise (control group)
2 balanced low-calorie diet and regular exercise in combination with the assumption of Garcinia mangostana (treatment group)

Throughout the duration of the study, every eight weeks, unless otherwise indicated from the specialists, for each subject was expected a nutritional and an endocrinological visit with a anthropometric parameter check (body composition) and compliance to therapy (dietary / physical activity diary). Also a bood sample test was performed to evaluate electrocardiogram, lipid profile, glucose tolerance, hormonal parameters, inflammatory and bone markers.

eligibility_section

Eligibility

Ages Eligible for Study:	18 Years to 65 Years (Adult)
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Obesity: BMI >35 kg/m2.
- Stable medical therapy for comorbidities from at least 6 months

Exclusion Criteria:

- Hormonal replacement therapy
- Hyperprolactinaemia and /or other endocrine hypothalamic-pituitary

diseases (empty sella syndrome and expansive pituitary disorders evaluated by MRI)

- Any other condition that medical judgment precludes patient safety

location_section

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

No Contacts or Locations Provided

more_info_section

More Information

Available Study Data/Document Available Study Data/Document

Responsible Party:	Carla Lubrano, Professor, University of Roma La Sapienza
ClinicalTrials.gov Identifier:	NCT02823561 History of Changes
Other Study ID Numbers:	URomLS-01
Study First Received:	June 23, 2016
Last Updated:	August 30, 2016
Health Authority:	Italy: Ethics Committee
Plan to Share Data Individual Participant Data Plan to Share IPD:	No

keywords mesh terms

Additional relevant MeSH terms:

Weight Loss
Obesity, Morbid
Body Weight Changes
Body Weight
Signs and Symptoms

ClinicalTrials.gov processed this record on October 07, 2016

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