Effects of a combined treatment with Glucomannan and Garcinia cambogia on patients with obesity

Submission date	Recruitment status	Prospectively registered
15/01/2018	No longer recruiting	[] Protocol
Registration date	Overall study status	Statistical analysis plan
17/01/2018	Completed	[] Results
Last Edited	Condition category	Individual participant data
17/01/2018	Nutritional, Metabolic, Endocrine	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Overweight and obesity are considered major health problems that contribute to a reduction in quality of life and increase mortality (death) risk. Both conditions have a high prevalence across the world reaching epidemic numbers. Weight loss supplements are becoming popular as a weight to lose fat. Garcinia cambogia (GC) is a fruit that has an ingredient that might incresae weight loss. Glucomannan (GNN) is an ingredient derived from a plant that is also marketed for weight loss. The aim of this study is to evaluate the effects of the administration of Garcinia cambogia (GC) and Glucomannan (GNN) on long-term weight loss in people with overweight or obesity.

Who can participate? Adults aged 18 and older who have a BMI over 25.

What does the study involve?

Participants have a balanced diet (Mediterranean diet), regular meals and intake of plenty of water. Standardised extracts of Garciania cambogia (52.4% Hydroxycitric acid) and Amorphophallus konjac (94.9%, Glucomannan) are administered separately in capsules of 500 mg each. Participants are treated with GC (500 mg), twice a day, half an hour before lunch and dinner and GNN (500 mg), twice a day, half an hour before lunch and dinner for six months. Participants are assessed for their weight and fat percentage.

What are the possible benefits and risks of participating? Participants may benefit in improvements in their condition. There are no direct risks with participating.

Where is the study run from? Scientifics Aesthetics Clinics of the body (Spain)

When is the study starting and how long is it expected to run for? June 2014 to October 2017 Who is funding the study? Universidad de Córdoba (Spain)

Who is the main contact? Professor José L Lancho (Scientific)

Contact information

Type(s) Scientific

Contact name Prof José L Lancho

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Contact details Department of Morphological Sciences School of Medicine University of Córdoba Avenida de Menéndez Pidal s/n Cordoba Spain 14071

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers GC/GNN-2

Study information

Scientific Title

Combined treatment of Garcinia cambogia and Glucomannan reduce weight, change body composition and ameliorate lipid and glucose blood profiles of people with overweight or obesity

Study objectives

Combined treatment reduces weight, changes body composition and ameliorate lipid and glucose blood profiles in overweight/obese patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Boards of Hospital Universitario Reina Sofia de Córdoba (Spain), 14/09/2014, ref: GC /GNN-2

Study design

Non randomized prospective trial evaluating differences between two dependent means (matches pairs design)

Primary study design Interventional

Secondary study design Non randomised study

Study setting(s) Hospital

Study type(s) Quality of life

Participant information sheet No participant information sheet available.

Health condition(s) or problem(s) studied

Obesity/overweight

Interventions

Participants have a balanced diet (Mediterranean diet), regular meals and intake of plenty of water. Standardised extracts of Garciania cambogia (52.4% Hydroxycitric acid) and Amorphophallus konjac (94.9%, Glucomannan) are administered separately in capsules of 500 mg each. Participants are treated with GC (500 mg), twice a day, half an hour before lunch and dinner and GNN (500 mg), twice a day, half an hour before lunch and dinner for six months.

Intervention Type

Supplement

Primary outcome measure

1. Weight is measured using digital balance (HD-305 TanitaTM) to the nearest 0.1 kg at baseline, three and six months of treatment

2. Fat mass is measured using a BioScan Spectrum operating at 50 KHz at baseline, three and six months of treatment

3. Visceral Fat mass is measured using the BioScan Spectrum operating at 50 KHz at baseline, three and six months of treatment

Secondary outcome measures

 Glucose (mg/dl) is measured from blood samples using a colorimetric enzyme assay method (CEPA® kits – MBiolog Diagnósticos Ltda.) at baseline, three and six months of treatment
Tryglerides (mg/dl) is measured from blood samples using using a colorimetric enzyme assay method (CEPA® kits – MBiolog Diagnósticos Ltda.) at baseline, three and six months of treatment

3. Cholesterol (mg/dl) is measured from blood samples using a colorimetric enzyme assay method (CEPA® kits – MBiolog Diagnósticos Ltda.) at baseline, three and six months of treatment

Overall study start date

01/06/2014

Completion date

01/10/2017

Eligibility

Key inclusion criteria

Males and females
Aged 18 years old
Have an BMI>25

Participant type(s)

Patient

Age group Adult

Lower age limit 18 Years

Sex

Both

Target number of participants 135

Key exclusion criteria

- 1. Pregnancy or lactation
- 2. Gastroplasty or gastrointestinal weight-reducing surgery
- 3. Stopped smoking during the past 6 months
- 4. Kidney disease
- 5. History of recurrent kidney stones
- 6. Liver dysfunction
- 7. Untreated high blood pressure
- 8. History or symptoms of gallstones
- 9. Cancer
- 10. History of endocrine disorders (particularly hypothyroidism)
- 11. History of bulimia and/or laxative abuse
- 12. Mental disorders with impaired independence
- 13. History of alcohol or other drug abuse

Date of first enrolment

08/01/2015

Date of final enrolment 08/01/2017

Locations

Countries of recruitment Spain

Study participating centre Scientifics Aesthetics Clinics of the body Avda. Periodista quesada Chacon numero 1 Cordoba Spain 14071

Sponsor information

Organisation University of Córdoba

Sponsor details

Department of Morphological Sciences School of Medicine Avenida de Menéndez Pidal s/n 14071 Córdoba Spain 14071

Sponsor type University/education

ROR https://ror.org/05yc77b46

Funder(s)

Funder type University/education

Funder Name Universidad de Córdoba

Results and Publications

Publication and dissemination plan

Planned submission to peer review evaluation to BMC pharmacology and toxicology.

Intention to publish date

01/04/2018

Individual participant data (IPD) sharing plan

In order to comply with Spanish law we can not describe this information unless a writing consent from each patient has been signed.

IPD sharing plan summary

Not expected to be made available