ISRCTN78807585 https://doi.org/10.1186/ISRCTN78807585

Effects of Garcinia cambogia/Glucomannan on weight loss

Submission date	Recruitment status	[_] Prospectively registered
08/09/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/09/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/11/2020	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Background and study aims
Overweight and obesity are considered major health problems that contribute to increase mortality (death) and quality of life. Both conditions have a high prevalence across the world reaching epidemic (widespread) numbers. Weight loss supplements are becoming popular as a weight to lose fat. Garcinia cambogia (GC) is a fruit that has an ingredient that is rumored to help with weight loss. Glucomannan (GNN) is an ingredient derived from a plant that is 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 are overweight.

What does the study involve?
Participants are told to keep a balanced diet, eat regular meals and drink plenty of water. Participants are told to ingest capsules of GC and capsules of GNN twice a day, half an hour before lunch and dinner for six months. Participants are told to exercise, avoid smoking and control their alcohol intake.

What are the possible benefits and risks of participating?
Participants may benefit from weight loss. There are no risks with participating.

Where is the study run from?
1. Scientifics Aesthetics Clinics of the body Córdoba (Spain)
2. Hospital e Maternidade São Francisco de Assis (Brazil)

When is the study starting and how long is it expected to run for?
February 2015 to March 2017

Who is funding the study?
University of Córdoba (Spain)

Who is the main contact?
Professor José Lancho

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
GC/GNN1

Study information

Scientific Title
Long-term effects of Garcinia cambogia/Glucomannan on weight loss in people with obesity, PLIN4, FTO and Trp64Arg polymorphisms

Study objectives
The aim of this study is to assess whether a controlled diet supplemented with GC and GNN was able to reduce weight after 3 and 6 moths in people with overweight or obesity. Another aim of this study is to evaluate if this reduction was modified by the presence in the patients of different genetic polymorphism related to FTO (rs9939609 A/T), PLIN4 (11482G>A) and ADRB3Trp64Arg.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethical Boards of Hospital Universitario Reina Sofia de Córdoba (Spain), 14/09/2014
2. Hospital e Maternidade São Francisco de Assis, Crato (Brasil), 21/01/2015

Study design

Multicentric, non randomized prospective trial, evaluating differences between two dependent means (matches pairs design)

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Obesity/overweight

Interventions
Participants are advised to 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 6 months. It was recommended to patients to practice physical exercise, avoid smoking, and control alcohol intake.

Intervention Type
Supplement

Primary outcome(s)
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
4. 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
5. 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
6. 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

Key secondary outcome(s))
Interaction of different polymorphism with primary outcome measures is measured using analysis of covariance or correlation through Pearson correlation test (for continuous variable such as age) at baseline, three and six months of treatment.

Completion date
08/03/2017

Eligibility

Key inclusion criteria
1. Males and females
2. Aged 18 years old
3. Have an BMC>25 and could be suffering dyslipidemias, hypertension, DM2 or their combinations

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
214

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
12/02/2015

Date of final enrolment
08/03/2015

Locations

Countries of recruitment
Brazil

Spain

Study participating centre
Scientifics Aesthetics Clinics of the body from Córdoba
Córdoba
Spain
14071

Study participating centre
Hospital e Maternidade São Francisco de Assis
Crato
Brazil
63105

Sponsor information

Organisation
University of Córdoba

ROR
https://ror.org/05yc77b46

Funder(s)

Funder type
University/education

Funder Name
University of Córdoba

Results and Publications

Individual participant data (IPD) sharing plan
Data related to this study are stored in Department of Morphological Sciences, School of Medicine, University of Córdoba, Spain. Mailing address: Avenida de Menéndez Pidal s/n 14071 Córdoba, Spain. Phone: +34 957218256.

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request. Prof, José L. Lancho at Department of Morphological Sciences, School of Medicine, University of Córdoba, Spain. Mailing address: Avenida de Menéndez Pidal s/n 14071 Córdoba, Spain. Phone: +34 957218256

All patients were informed and signed the proper informed consent. This work was in accordance with Helsinki declaration. Participant information was encrypted assigning different numbers to each participant. Participant personal information is protected by spanish law (Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal)

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/01/2018	25/11/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes