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Mangosteen juice blend for the reduction of inflammation in obese subjects

Submission date	Recruitment status	[ ] Prospectively registered
21/07/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/08/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/08/2009	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
XANG1000

Study information

Scientific Title
Mangosteen juice blend for the reduction of inflammation in obese subjects: a randomised, double-blind, placebo-controlled, dose finding study

Study objectives
The hypothesis of this study is that XanGo™ Juice (a proprietary juice blend containing mangosteen juice) will reduce inflammation and increase antioxidant levels in obese subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board (IRB) approval obtained from the Copernicus Group (Cary, NC) on the 11th July 2007 (ref: MED4-07-299)

Study design
Randomised double-blind placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Metabolic syndrome/obesity

Interventions
This is a randomised, double-blind, placebo-controlled 8-week study with a 2-week pre-study washout period. The study included four groups including placebo and three doses of test product. The study was conducted at a single site Medicus Research clinical research center, Northridge, CA, USA.

The test product was XanGo™ Juice produced by XanGo, LLC. The primary ingredient was mangosteen (Garcinia mangostana L.) whole fruit puree. Other ingredients were apple fruit juice, pear fruit juice, grape fruit juice, pear fruit puree, blueberry fruit juice, raspberry fruit juice, strawberry fruit juice, cranberry fruit juice, and cherry fruit juice. The placebo consisted of water, sucrose (3 g/30 ml), citric acid, red grape juice concentrate, fibre complex, grape skin, natural flavours, red #40, cloud (ester gum), whey protein isolate, sodium benzoate, xanthan gum, blue #1, and caramel color. Three different dosages of the juice were tested and compared to placebo. The product doses tested were 3 oz, 6 oz and 9 oz. All doses and placebo were consumed in a total of 9 oz of liquid in identical bottles. The placebo was used to make up the volume for the lower doses. Subjects were instructed to consume the assigned drink twice a day, once in the morning and again in the evening. They therefore took a total of 0 to 18 oz of active product per day in 18 oz of fluid for 8 weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
XanGo™ Juice

Primary outcome(s)
Efficacy of multiple doses of XanGo™ Juice compared to placebo on inflammation as measured by levels of HS-CRP and cytokines (interleukin [IL]-1, IL-2, IL-4, IL-6, IL-7, IL-8, IL-10, IL-12,

interferon (IFN)-gamma and tumour necrosis factor (TNF)-alpha). All outcomes measured at baseline, 4 weeks and 8 weeks.

Key secondary outcome(s))
Oxidative stress via F2 isoprostance in urine. All outcomes measured at baseline, 4 weeks and 8 weeks.

Completion date
01/05/2008

Eligibility

Key inclusion criteria
1. Aged between 30 - 75 years of age, either sex
2. Body mass index (BMI) greater than 30 and less than 45 kg/m^2 (obese)
3. A high sensitivity C-reactive protein (HS-CRP) of greater than 3
4. Agreed to discontinue anti-inflammatory medications and supplements (other than daily 81 mg aspirin, which was allowed)
5. Agreed to use approved birth control methods if a female of childbearing age
6. Agreed to not initiate or change any exercise or diet programs during the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Subjects were excluded if they had consumed the test product in the past
2. Had allergies to the test product
3. Using any drugs that can affect CRP
4. Were taking hormone replacements, anticoagulants or anti-platelet therapy
5. Had surgery in the past 6 months
6. Smoked cigarettes
7. Known alcohol or drug abuse
8. Had major systemic, inflammatory or chronic disease
9. Untreated depression
10. Active eating disorder
11. Unable to understand or follow study protocol
12. Pregnant or lactating
13. Any medical condition which, in the opinion of the investigator, might interfere with the subject's ability in the trial

Date of first enrolment

01/09/2007

Date of final enrolment
01/05/2008

Locations

Countries of recruitment
United States of America

Study participating centre
18250 Roscoe Blvd. Suite 240
Northridge
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91325

Sponsor information

Organisation
XanGo, LLC (USA)

ROR
https://ror.org/041mqc477

Funder(s)

Funder type
Industry

Funder Name
XanGo, LLC (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration