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Effects of chia seeds on blood cholesterol and triglyceride levels

Submission date	Recruitment status	[ ] Prospectively registered
15/02/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/02/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/02/2017	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Eating food that contains a lot of fat can lead to hyperlipidemia, which means there are high levels of lipids (fats) in the blood. High cholesterol can cause blood clots, heart attacks and strokes. Foods that can help lower cholesterol have become popular, especially foods that are high in omega-3 and omega-6 fatty acids. These nutrients are usually found in plant oils and fish. Since Western diets are usually low in fish, it is important to look at alternative sources of omega 3 and 6. Chia seeds (small brown/black seeds found in Mexico and Guatemala) contain high levels of omega-3 and omega-6, almost similar to fish. Some research has found that they have able to lower plasma lipid levels (fat in the blood). The aim of this study is to evaluate the effects of chia seeds based food supplements on lipid plasma levels.

Who can participate?
Men and women who are slightly hyperlipidemic (higher level of fat in the blood) between 18-83 years old

What does the study involve?
All participants fill out a food frequency questionnaire at the beginning of the study and then are asked to consume a food containing no omega 3 or 6 every day for a month. They are then randomly allocated to one of five groups. Those in group one eat five grams of chia seeds daily for two months. Those in group two eat five grams of micronized chia seeds daily for two months. Those in group three eat two grams of a food product that has monocomponent chia seeds daily for two months. Those in group four eat two grams of a food product that has multicomponent chia seeds daily for two months. Those in group five eat 60mg of vitamin E daily for two months. Participants are asked to fast for 12 hours before they give blood samples at the beginning of the study and at week 4, 8, 12 and 16. Participants are followed up to see how the chia seeds affect their blood lipid levels.

What are the possible benefits and risks of participating?
Participants may benefit from a positive nutritional impact of eating chia seeds. There are no notable risks involved with participating

Where is the study run from?
Samnium Medical Cooperative (Italy)

When is the study starting and how long is it expected to run for?
February 2016 to June 2017

Who is funding the study?
1. Samnium Medical Cooperative (Italy)
2. Depatment of Pharmacy, University of Naples “Federico II” (Italy)

Who is the main contact?
Prof. Gian Carlo Tenore

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
22.02.2016 26875

Study information

Scientific Title
Effects of CHIA SEED based nutraceutical products on LIPID metabolism in healthy subjects

Acronym
CHIA SEED LIPID

Study objectives
The aim of this study is to evaluate the effects of chia seed based nutraceutical products on lipid plasma levels in the subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Azienda Ospedaliera Gaetano Rummo Hospital, 22/02/2016, ref: 26875

Study design
Interventional randomised parallel controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Metabolic Syndrome (MeTS)

Interventions
Participants are asked to fill out a food frequency questionnaire at the beginning of the study. Participants in all groups eat a placebo daily for one month. Participants are then randomly allocated into one of five groups.

Group 1: Participants are instructed to consume five grams of chia seeds per day for two months.
Group 2: Participants are instructed to consume five grams micronized chia seeds per day for two months.
Group 3: Participants are instructed to consume two grams of monocomponent chia seed based nutraceutical (similar to a food supplement) per day for two months.
Group 4: Participants are instructed to consume two grams of multicomponent chia seed based nutraceutical (similar to a food supplement) per day for two months.
Group 5: Participants are instructed to consume 60 milligrams of vitamin E per day for two months.

Participants are followed up with blood tests and food frequency questionnaires after 4, 6, 8, 12 and 16 weeks (in which they are asked to fast for 12 hours before the test) to see if eating chia seeds impacts their lipid plasma levels.

Intervention Type
Supplement

Primary outcome measure
1. Plasma TC is measured using a blood test (analysis by spectrophotometer) at baseline, 4, 8, 12 and 16 weeks
2. HDL-C is measured using a blood test (analysis by spectrophotometer) at baseline, 4, 8, 12 and 16 weeks
3. LDL-C is measured using a blood test (analysis by spectrophotometer) at baseline, 4, 8, 12 and 16 weeks
4. Triglyceride levels are measured using a blood test (analysis by spectrophotometer) at baseline, 4, 8, 12 and 16 weeks

Secondary outcome measures
1. Clinical history is measured by interviews and previous clinical data at baseline
2. Anthropometric measures are measured by taking height and weight at baseline, 4, 8, 12 and 16 weeks
3. Nutrient intake and dietary habits are measured using a seven day food record validated nutritional questionnaire at baseline, 4, 8, 12 and 16 weeks
4. Blood pressure is measured using a blood pressure cuff at baseline, 4, 8, 12 and 16 weeks
5. 24 hour ambulatory blood pressure is measured using blood pressure cuff at baseline, 4, 8, 12 and 16 weeks
6. Blood levels (AST, ALT, γ-GTP, ALP, LDH, Albumin, Total bilirubin, Creatinine) are measured using a blood test (analysis by spectrophotometer) at baseline, 4, 8, 12 and 16 weeks

Overall study start date
01/02/2016

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Aged 18-83 years old
2. Caucasian
3. Have the following range values of serum cholesterol parameters at baseline:
3.1. TC, 200-260 mg/dL
3.2. HDL-C, 31-45 mg/dL
3.3. LDL-C, 190-205 mg/dL
3.4. TG, 170-280 mg/dL
4. Body mass index (BMI) between 18 and 30 kg/m2

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit

18 Years

Upper age limit
83 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Smoking
2. Obesity (BMI >30 kg/m2)
3. Diabetes
4. Hepatic disease
5. Renal disease
6. Heart disease
7. Family history of chronic diseases
8. Drug therapy or supplement intake for hypercholesterolemia
9. Drug therapy or supplement intake containing apple polyphenols
10. Heavy physical exercise (more than10 hours per week)
11. Pregnant women, women suspected of being pregnant, women who hoped to become pregnant, breastfeeding
12. Birch pollen allergy
13. Use of vitamin/mineral supplements 2 weeks prior to entry into the study
14. Donation of blood less than 3 months before the study

Date of first enrolment
16/02/2017

Date of final enrolment
28/02/2017

Locations

Countries of recruitment
Italy

Study participating centre
Samnium Medical Cooperative
Viale C.Colombo 18
Benevento
Italy
82037

Study participating centre

Department of Pharmacy, University of Naples “Federico II”
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Sponsor information

Organisation
Samnium Medical Cooperative

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02ww5xj89

Funder(s)

Funder type
Research organisation

Funder Name
Samnium Medical Cooperative

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from: Gian Carlo Tenore giancarlo.tenore@unina.it

IPD sharing plan summary

Available on request