

# Effects of chia seeds on blood cholesterol and triglyceride levels

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<b>Registration date</b> 21/02/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/02/2017	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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. Department of Pharmacy, University of Naples "Federico II" (Italy)

Who is the main contact?  
Prof. Gian Carlo Tenore

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Gian Carlo Tenore

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## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Prevention

### **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(s)**

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

### **Key secondary outcome(s)**

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,  $\gamma$ -GTP, ALP, LDH, Albumin, Total bilirubin, Creatinine) are measured using a blood test (analysis by spectrophotometer) at baseline, 4, 8, 12 and 16 weeks

**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/m<sup>2</sup>

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

83 years

**Sex**

All

**Key exclusion criteria**

1. Smoking
2. Obesity (BMI >30 kg/m<sup>2</sup>)
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 than 10 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"**

Via Domenico Montesano 49

Naples

Italy

80131

## **Sponsor information**

**Organisation**

Samnium Medical Cooperative

**ROR**

<https://ror.org/02ww5xj89>

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

Samnium Medical Cooperative

## **Results and Publications**

### **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](mailto:giancarlo.tenore@unina.it)

### **IPD sharing plan summary**

Available on request