

# Effects of chia seeds on acne

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<b>Registration date</b> 14/03/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/03/2017	<b>Condition category</b> Skin and Connective Tissue Diseases	<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

Acne vulgaris is a common skin condition which causes spots to develop on the skin, usually the face, chest and back. Some cases of acne can cause large lesions (pustules) that can leave scars. It is the most common skin disease that is treated by physicians. Although it is easy to diagnose, the nature of acne vulgaris means that there is no one simple way to evaluate its severity. Acne is no longer considered a teenager problem as it can affect men and women of all ages.

Some of the underlying causes are excessive sebum (oils), bacteria, hormones, stress and diet. A very important factor that causes acne is inflammation (swelling). Research has shown that the influence of diet on the development of acne could be associated to inflammation. The typical treatments for acne are usually topical medications (creams and gels that are applied to the body), ultraviolet radiation (shining a specific light directly on the skin) and oral (taken by mouth) medications. In addition to traditional therapies, many natural remedies have been made to act directly on the disorder and are antioxidant, restorative and anti-inflammatory. The underlying processes are complex but they show that inflammatory action could be stopped as there are specific enzymes that transform fatty acids (mainly omega 3 and 6) into compounds able to stop the inflammatory process. Studies have shown that omega-3 fatty acids play a major role in anti-inflammatory processes even more than omega-6 acids, therefore there should be an increase of omega-3 intake in diets. The ideal ratio of omega-3 and omega-6 fatty acids suggested for diets is 1.8:1. However, Western diets really lack fatty acids as they food eaten does not contain a high amount of them. Chia seeds (small brown/black seeds found in Mexico and Guatemala) are naturally rich in parent omega 3 (alpha-linolenic acid) and therefore have the potential to help treat inflammatory disorders. The aim of this study is to evaluate the effects of a nutraceutical product made with chia seeds on acne lesions.

### Who can participate?

Adults between the ages of 18-65 with chronic acne.

### 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 omega 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 four, eight, 12 and 16. Participants are followed up to see how the chia seeds affect their acne lesions.

What are the possible benefits and risks of participating?

Participants may benefit from a reduction in acne lesions. There are no notable risks involved with participating.

Where is the study run from?

1. Samnium Medical Cooperative (Italy)
2. Department of Pharmacy, University of Naples "Federico II" (Italy)

When is the study starting and how long is it expected to run for?

April 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?

Professor Gian Carlo Tenore

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Gian Carlo Tenore

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## Additional identifiers

**Protocol serial number**

19.04.2016 57994

## Study information

**Scientific Title**

Effects of CHIA SEED based nutraceutical products on ACNE lesions plaques in a randomised trial

**Acronym**

CHIASEEDACNE

**Study objectives**

The aim of the study is to evaluate the effects of chia seed based nutraceutical products on acne lesions in human subjects.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Azienda Ospedaliera Gaetano Rummo Via dell'Angelo,19/04/2016, ref: 57994

**Study design**

Open interventional parallel randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Prevention

**Health condition(s) or problem(s) studied**

Acne lesions

**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 acne severity.

**Intervention Type**

Supplement

**Primary outcome(s)**

Severity of acne lesions are measured using the Global Acne Grading System (GAGS) score at baseline and 16 weeks.

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

1. Clinical history is measured both by interviews and previous clinical data at baseline
2. Itchiness is measured using Visual Analogue Scale (VAS) 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 baseline, 4, 8, 12, and 16 weeks
6. Blood analysis (AST, ALT,  $\gamma$ -GTP, ALP, LDH, Albumin, Total bilirubin, Creatinine) is measured using a blood test (analysis by a spectrophotometer) at baseline, 4, 8, 12, and 16 weeks

### **Completion date**

30/06/2017

## **Eligibility**

### **Key inclusion criteria**

1. Men and women between 18-65 years of age
2. Caucasian
3. Chronic acne lesions of any severity (treated and untreated)

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

65 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. Heavy physical exercise (>10 h/week)
9. Pregnant women, women suspected of being pregnant, women who hoped to become pregnant, breastfeeding
10. Birch pollen allergy
11. Use of vitamin/mineral supplements 2 weeks prior to entry into the study
12. Donation of blood less than 3 months before the study

**Date of first enrolment**

23/02/2017

**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" (lead centre)**

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80131

## Sponsor information

**Organisation**

Samnium Medical Cooperative

**ROR**

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

## Funder(s)

**Funder type**

Not defined

**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 Prof Gian Carlo Tenore [giancarlo.tenore@unina.it](mailto:giancarlo.tenore@unina.it)

**IPD sharing plan summary**

Not expected to be made available