ISRCTN26733572 https://doi.org/10.1186/ISRCTN26733572

Effects of chia seeds on acne

Submission date
21/02/2017

Recruitment status
No longer recruiting

Registration date
14/03/2017

Overall study status
Completed

Last Edited
14/03/2017

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 additional 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Secondary outcome measures
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, γ-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

Overall study start date
01/04/2016

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

Age group
Adult

Lower age limit

18 Years

Upper age limit
65 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. 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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Naples
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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
Not defined

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 Prof Gian Carlo Tenore giancarlo.tenore@unina.it

IPD sharing plan summary

Not expected to be made available