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Effects of chia seeds on psoriasis

Submission date
21/02/2017

Recruitment status
No longer recruiting

Registration date
22/02/2017

Overall study status
Completed

Last Edited
22/09/2017

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Psoriasis is a common inflammatory skin condition that causes red, flaky, crusty patches of skin covered with silvery scales in the knees, lower back/hip area, elbows, hands, feet, and scalp. Psoriasis is usually caused by a genetic predisposition (something in your DNA that makes you to be more likely to get it) and different environmental factors. There are three different treatments for psoriasis: topical, phototherapy and systemic. Topical treatments involve applying medication directly on the skin, such as a cream or gel. Phototherapy involves shining a specific light on the skin in combination with a tablet or cream containing psoralen (a medication made from plants that make the skin more sensitive to light). Systemic treatment involves taking antinflammatory and/or immunosuppressant medications (medications that try to prevent the body's natural way of fighting off bacteria and disease). In addition to these treatments, there are natural therapies that try to address the cause of psoriasis. The biochemical mechanisms that cause inflammation are very complex. There are specific enzymes that transform fatty acids (mainly omega 3 and 6) into compounds able to stop the inflammatory process. Recent studies have shown that omega 3 fatty acids could be helpful for those with psoriasis. As western diets are low in omega 3 fatty acids, specific foods and food supplements rich in omega 3 fatty acids could help improve the symptoms of psoriasis. Chia seeds (small brown/black seeds found in Mexico and Guatemala) are rich in precursors of omega 3 and omega 6 fatty acids which play a role in inflammation. The aim of this study is to evaluate the effects of chia seeds based food supplements as tools to provide high amounts of these antinflammatory compounds, with the aim of reducing psoriasis.

Who can participate?
Caucasian men and women aged between 18-83 years old.

What does the study involve?
Participants are randomly allocated to one of five groups. 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. 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. Photographs are taken of their lesions at the beginning and at the end of the

study. 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 psoriasis.

What are the possible benefits and risks of participating?
Participants may benefit from a reduction in psoriatic plaque. 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?
March 2017 to June 2016

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
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Contact information

Type(s)
Scientific

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Protocol serial number
19.04.2016 57993

Study information

Scientific Title

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

Acronym
CHIASEEDPSOR

Study objectives
The aim of this study is to evaluate the effects of chia seed based nutraceutical products on psoriatic plaques in human subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Azienda Ospedaliera Gaetano Rummo Via dell'Angelo, 19/04/2016, ref: 57993

Study design
Interventional randomised parallel controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Psoriatic plaques

Interventions
Participants have photographs taken of their psoriasis lesions and the severity of their symptoms is measured. Participants undergo a clinical evaluation and fill out a questionnaire about dietary habits at the beginning of the study. They are then instructed to consume a placebo daily for one month. After the one month of consuming a placebo, participants are randomly allocated to 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 of micronized chia seeds per day for two months.
Group 3: Participants are instructed to consume two grams of monocomponent chia seed based nutraceutical per day for two months.
Group 4: Participants are instructed to consume two grams of multicomponent chia seed based nutraceutical per day for two months.
Group 5: Participants are instructed to consume 200 mg salicylate extract per day for two months.

A follow up period of one month is planned for each group. Photographs are taken of the lesions at the end of the study. Participants are followed up with a blood test (in which they are asked to fast for 12 hours before the test) and clinical visits at 4, 6, 8, 12 and 16 weeks to see if eating chia seeds reduced the size of the psoriasis.

Intervention Type
Supplement

Primary outcome(s)
Size of erythema, desquamation and the size of the plaque being surveyed is measured using the Psoriasis Area Severity Index (PASI) at baseline, 4, 8, 12, and 16 weeks

Key secondary outcome(s))
1. Clinical history is measured both by interviews and previous clinical data at baseline
2. The reduction of itch 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 spectrophotometer) at baseline, 4, 8, 12, and 16 weeks

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Men and women between 18-83 years of age
2. Caucasian
3. Chronic plaque psoriasis 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
83 years

Sex
All

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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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

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes