Study Identification

Unique Protocol ID: UACJ-ICB-2016-01
Brief Title: Hypolipidemic and Antioxidant Capacity of Spirulina and Exercise
Official Title: Independent and Synergistic Effect of Spirulina Maxima With Exercise on General Fitness, Lipid Profile and Antioxidant Capacity in Overweight and Obese Subjects

Secondary IDs:

Study Status

Record Verification: March 2017
Overall Status: Not yet recruiting
Study Start: May 2017 []
Primary Completion: September 2017 [Anticipated]
Study Completion: December 2017 [Anticipated]

Sponsor/Collaborators

Sponsor: Universidad Autonoma de Ciudad Juarez
Responsible Party: Sponsor
Collaborators:

Oversight

U.S. FDA-regulated Drug:
U.S. FDA-regulated Device:
IND/IDE Protocol: No
Human Subjects Review: Board Status: Approved
Approval Number: CBE.ICB/062.09-15
Board Name: Comide de Bioetica
Board Affiliation: Investigacion y Posgrados del ICB
Phone: 6566881800
Email: rbarreno@uacj.mx
Address: Plutarco Elias Calles S/N

Data Monitoring: Yes
Study Description

Brief Summary: The purpose of this study is to demonstrate that Spirulina maxima intake and a dosed physical activity program will decrease, both independently and synergistically, cardiovascular risks (Dyslipidemias and oxidative stress) in overweight and obese subjects.

Detailed Description: Cardiovascular diseases are the leading cause of death globally, being dyslipidemias, oxidative stress, sedentary lifestyle and obesity primary risk factors. As a way to reduce cardiovascular diseases risk factors, the intake of antioxidants that come from a fruit and vegetable-rich diet or nutritional supplements, have been proposed; in this sense, the cyanobacterium Spirulina maxima is an important source of antioxidants, which is currently associated with cardiovascular protection properties. Furthermore, physical exercise at moderated intensity has protective effect exerted against cardiovascular diseases risks, mainly due to physiological adaptations, including expression of antioxidant enzymes, which stop formation and propagation of radicals, improving redox status of the organism.

There is evidence that Spirulina maxima, in addition to exercise, decreases cardiovascular diseases risks, this was mainly observed in animal models. However, no studies in humans under Spirulina maxima and exercise experimental designs proving these benefits are reported. Therefore this study will analyze the independent and synergistic effect of the intake of Spirulina maxima with a program of physical exercise at moderated intensity on general fitness, plasma lipid profile and antioxidant capacity in overweight and obese subjects.

Methods/design: Through a randomized, double blind, placebo controlled, counterbalanced crossover study design, 80 healthy overweight and obese subjects will be assessed during a 12 week isoenergetic diet, accompanied by 4.5 g/day Spirulina maxima intake and/or a systematic physical exercise program at moderate intensity. Body composition, VO2 consumption, heart rate, blood lactate, plasma concentrations of triacylglycerols, total, low and high-density lipoprotein cholesterol, antioxidant status, lipid oxidation, protein carbonyls, superoxide dismutase, catalase, glutathione, glutathione peroxidase, glutathione reductase, and paraoxonase will be assessed.

Discussion: Spirulina maxima and exercise are good alternatives to improve general fitness, to prevent or lessen dyslipidemia and oxidative stress in subjects with risk factor of chronic or noncommunicable diseases. However the independent and synergistic effect of Spirulina maxima with exercise against dyslipidemias and stress in overweight and obesity is not yet known.

Conditions

Conditions: Cardiovascular Diseases

Keywords:

Study Design

Study Type: Interventional
Primary Purpose: Treatment
Study Phase: Phase 1
Interventional Study Model: Crossover Assignment
Number of Arms: 2
Masking: Participant, Investigator
Allocation: Randomized
Enrollment: 80 [Anticipated]

### Arms and Interventions

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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| Active Comparator: Exercise group and supplementation | Dietary Supplement: Supplementation with Spirulina maxima  
Supplementation with placebo  
Group with exercise program and supplementation with Spirulina maxima or placebo (4.5 g/d) in capsules during 6 weeks, then a 2 weeks washout, to finally proceed to the other treatment during 6 more weeks. During the 14 weeks of study duration every participant will have a personal isoenergetic diet. |
|  |  
Dietary Supplement: Supplementation with Spirulina maxima  
Supplementation with placebo  
Group with exercise program  
(4.5 g/d) in capsules during 6 weeks.  
Washout  
2 weeks washout period to each study subject to avoid any possible carryover effect.  
Supplementation with placebo  
Supplementation with placebo (4.5 g/d) in capsules during 6 weeks.  
Isoenergetic diet  
All participants will have a personal isoenergetic diet according to their height, weight, body composition and daily physical activity during 14 weeks  
Exercise program  
Participants are going to exercise five days a week with the following protocol: Between 5 and 10 min of heating exercise, Between 20-30 min anaerobic exercise and 20-30 min of aerobic exercise (cardiovascular exercise): walking, jogging, running and/or cycling, Three days a week aerobic intensities will be between 60% and 80% and two days between 70% and 90% of the maximum heart rate reserve, and five final minutes of stretching. |
| Active Comparator: No exercise group and supplementation | Dietary Supplement: Supplementation with Spirulina maxima  
Supplementation with placebo  
Group without exercise program and supplementation with Spirulina maxima or placebo (4.5 g/d) in capsules during 6 weeks, then a 2 weeks washout, to finally proceed to the other treatment during 6 more weeks. During the 14 weeks of study duration every participant will have a personal isoenergetic diet. |
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Dietary Supplement: Supplementation with Spirulina maxima  
Supplementation with placebo  
Group without exercise program  
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Isoenergetic diet  
All participants will have a personal isoenergetic diet according to their height, weight, body composition and daily physical activity during 14 weeks |

### Outcome Measures

**Primary Outcome Measure:**
1. Change in lipid profile
Change in plasma triacylglycerols, total cholesterol, high density lipoproteins cholesterol, and low density lipoproteins cholesterol after each treatment by using standardized enzymatic methods

[Time Frame: 14 weeks]

Secondary Outcome Measure:

2. General fitness assessed by change in maximum oxygen consumption
   Change in maximum oxygen consumption by using a gas analyzer (Cortex Metalizer 3B)
   [Time Frame: 14 weeks]

3. General fitness assessed by change in heart rate
   Change in heart rate by using a pulsometer (Polar HT7)
   [Time Frame: 14 weeks]

4. General fitness assessed by change in lactate
   Change in lactate concentration by using an automatized method (YSI lactate analyzer-1600)
   [Time Frame: 14 weeks]

5. General fitness assessed by change in body mass
   Change in body fat mass and body lean mass by using pletysmography (BOD-POD)
   [Time Frame: 14 weeks]

6. General fitness assessed by change in blood pressure
   Change in blood pressure by using an aneroid sphygmomanometer (Edimetric, Medical Technologies)
   [Time Frame: 14 weeks]

7. Redox status assessed by change in malondialdehyde
   Change in malondialdehyde concentration by using standardized specific methods
   [Time Frame: 14 weeks]

8. Redox status assessed by change in protein carbonyls
   Change in protein carbonyls concentration by using standardized specific methods
   [Time Frame: 14 weeks]

9. Redox status assessed by change in paraoxonase
   Change in paraoxonase concentration by using standardized specific methods
   [Time Frame: 14 weeks]

10. Redox status assessed by change in superoxide dismutase
    Change in superoxide dismutase concentration by using standardized specific methods
    [Time Frame: 14 weeks]

11. Redox status assessed by change in catalase
    Change in catalase concentration by using standardized specific methods
    [Time Frame: 14 weeks]

12. Redox status assessed by change in glutathione
    Change in glutathione concentration by using standardized specific methods
    [Time Frame: 14 weeks]

13. Redox status assessed by change in glutathione reductase
    Change in glutathione reductase concentration by using standardized specific methods
    [Time Frame: 14 weeks]

14. Redox status assessed by change in glutathione peroxidase
    Change in glutathione peroxidase concentration by using standardized specific methods
    [Time Frame: 14 weeks]
Eligibility

Minimum Age: 18 Years
Maximum Age: 35 Years
Sex: All
Gender Based:
Accepts Healthy Volunteers: Yes

Criteria: Inclusion Criteria:

• Overweight (Body mass index (BMI): 25-29.9 kg/m2) and obese (BMI: > 30 kg/m2) persons

Exclusion Criteria:

• Taking drugs and/or food or vitamin supplements
• diabetes
• have a physical or electrocardiographic injury that prevents them from engaging in regular physical exercise

Contacts/Locations

Central Contact Person: Arnulfo Ramos-Jimenez, PhD
Telephone: 6561679309
Email: aramos@uacj.mx

Central Contact Backup: Marco A Hernandez-Lepe, MS
Telephone: 6562159803
Email: qblepe@hotmail.com

Study Officials: Marco A Hernandez-Lepe, MS
Study Principal Investigator
Universidad Autonoma de Ciudad Juarez

Arnulfo Ramos-Jimenez, PhD
Study Director
Universidad Autonoma de Ciudad Juarez

Locations: Mexico
Universidad Autonoma de Ciudad Juarez
Juarez, Chihuahua, Mexico, 32310
Contact: Barraza Patricia, Dra
Contact: Amaelvi Arce, Lic
mbarraza@uacj.mx
E-mail: aarce@uacj.mx

Principal Investigator: Veronica Portillo, MA
Sub-Investigator: Miguel Perez, PhD
Sub-Investigator: Yolanda Loya, PhD

References


Links: URL: http://www.who.int/mediacentre/factsheets/fs317/en/

Description Statistics World Health Organization (WHO)

Study Data/Documents: