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Health effects of dietary supplementation of Sujiaonori (Ulva Profilera Muller) biomaterials on salivary adiponectin, cardiovascular risk parameters and skin health in healthy humans

Submission date
04/08/2016

Recruitment status
No longer recruiting

Registration date
15/09/2016

Overall study status
Completed

Last Edited
10/10/2023

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
In Japan, a lot of vegetables and seaweeds are eaten daily and the Japanese diet is known to promote good health. 'Sujiaonori' is an edible green river alga that mainly grows in the Shimanto River, Kochi prefecture, in an area where the salty sea water is mixed with the soft water from Kochi Mountains. This gives Sujiaonori its special flavor and taste. Shimanto River is also well-known in Japan as one of the rivers with cleanest water in the country. Previous research have shown the health effects of Ulva species growing in rivers in Japan, including Ulva (Enteromorpha) prolifera; however, to date, information on how it may boost the immune system and also the antioxidant, anti-inflammatory and anticancer effects of ulval biomaterials are all from animal studies only. Ulva biomaterials (ulvans or sulfated polysaccharides in particular), are reported to improve the lipid profile (how much fat there is in the body) and diabetes in rats. They therefore have the potential to reduce cardiovascular and metabolic (for example, diabetes) risks. This study is looking at the effects of dietary intake of sujiaonori biomaterial supplement on adiponectin (body fat) production, cardiometabolic profile (that is, whether a person is likely to develop cardiovascular disease, become overweight or develop diseases such as type 2 diabetes) and skin health in healthy humans.

Who can participate?
Healthy university students or staff aged at least 20

What does the study involve?
Each participant is randomly allocated to one of two groups. Those in group 1 are given supplement powder packs containing dried sujiaonori powder to take twice a day, every day, for 28 days at meal times. Those in group 2 are given powder packs containing a placebo to take twice a day, every day, for 28 days at meal times. All participants are asked to provide saliva samples on day 1 of the study and day 28. These are later used for analysis. They are also asked to fill in questionnaires on their general health and diet, again on days 1 and 28 of the study.

What are the possible benefits and risks of participating?
Potential benefits for each participant include feedback regarding health and diet. There are no potential risks
given that biological specimens are saliva samples, which are obtained through a non-invasive technique.

Where is the study run from?
University of Kochi (Japan)

When is the study starting and how long is it expected to run for?
February 2016 to August 2016

Who is funding the study?
Kochi Prefectural Government (Japan)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Approval number 15-10

Study information

Scientific Title
Effects of daily intake of Sujiaonori (Ulva prolifera Muller) supplement on salivary adiponectin, cardiometabolic risk and skin health in healthy humans: a four-week placebo-controlled trial

Acronym
Sujiaonori Clinical Study1

Study objectives
The aim of this study is to investigate whether daily Sujiaonori biomaterial supplementation can improve adiponectin production, cardiovascular and metabolic risk markers and skin health in apparently healthy humans.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval from the Scientific Ethics Committee of the Faculty of Nutrition, 10/11/2015, ref: 15-10

Primary study design
Interventional

Study design
Investigator-blinded non-randomized placebo-controlled single-center clinical trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Cardiometabolic risk markers and skin health

Interventions
Forty male and female university students and staff who freely accepted to participate in this study are enrolled. At day 1 of the study (baseline), each participant is given an envelope on which his/her registration number is written; this envelope contains two survey questionnaires (described below), a pen and a number of supplement powder packs to be taken twice a day (3gr during breakfast and 3gr during dinner) for 28 days (each pack contains 3gr of dried sujiaonori powder for the study group; or 3gr of placebo powder made of 70% corn starch mixed with 30% Japanese spinach to give it a green color). What supplement pack set each participant is given is allocated randomly.

At day 1 and day 28, each participant provides saliva sample in a prepared saliva tube. Tubes are stored at -20 degrees Celsius in a refrigerator at the clinical room. Elisa assay will be performed using Elisa kits from a Japanese provider for measurement of salivary adiponectin and alpha-amylase levels, at the end of study.

1. Survey questionnaires:
1.1. Current health status survey questionnaire: it comprises questions related to:
1.1.1. Demographics, anthropometric and clinical parameters (age, gender, occupation, BMI, systolic and diastolic blood pressure, history of hypertension, gastrointestinal functional disorders such as chronic constipation, diarrhea and dyspepsia); measurement of weight, height, blood pressure are performed 3 times and results are written at indicated locations on the survey sheet by the volunteer him/herself
1.1.2. Lifestyle-related information and vital signs (smoking habit, alcohol consumption, blood pressure, and health complaints)

1.1.3. History of hypertension (volunteers should report whether they recently had high blood pressure days or weeks before joining this study)
1.1.4. Physical activity in a week, its frequency and duration (they should indicate how often they exercise and how long it takes)
1.1.5. Trans Epidermal Water Loss or TEWL (use of corneometer, Cutometer dual MPA, a sensitive device connected to a computer that is placed on external area of left arm to measure permeability of skin twice, as shown in Figure 3; the best TEWL value is then written at indicated place on the survey sheet. TEWL measurement is performed by a dermatologist)
1.1.6. Intake of Suji-aonori (each volunteer indicates whether he has been eating aonori prior to this study; if yes, he/she mentions the frequency)
1.2. Dietary history assessment questionnaire (BDHQ):
This is a new version of 'food frequency questionnaire (FFQ)' developed by the School of Public Health, University of Tokyo, and it is currently widely used in Nutrition surveys. Both the 'current health status questionnaire' and the BDHQ were anonymously completed by each study participant.

Intervention Type
Supplement

Primary outcome(s)
1. Salivary adiponectin and alpha-amylase levels, measured by ELISA at baseline and 28 days
2. Trans-epidermal water loss (TEWL), assessed via 3 measurements performed by a dermatologist (the best TEWL value was considered), by Cutometer dual MPA at baseline and 28 days

Key secondary outcome(s)
1. Blood pressure, measured using an electronic manometer (OMRON HEM-7321-E) at baseline and 28 days
2. BMI is measured using height and weight measurements at baseline and 28 days
3. Current health status, assessed using a survey questionnaire designed for the purpose of this study and the 'Dietary history assessment questionnaire (BDHQ)' (a validated Japanese version of Food frequency questionnaire developed by the School of Public Health, Tokyo University, Japan) at baseline and 28 days

Completion date
30/08/2016

Eligibility

Key inclusion criteria
1. Aged 20 years or older
2. University student or staff
3. No major health conditions (heart, liver, brain, kidney disease or diabetes)
4. Not taking any medication
5. Provision of written informed consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 Years

Sex
All

Total final enrolment
32

Key exclusion criteria
1. Known major health condition
2. Taking medication
3. Those who might not be able to attend on day 0 and 28 for saliva sampling and clinical evaluation
4. Personal or family history of sensitization or allergy to any algal food product

Date of first enrolment
26/02/2016

Date of final enrolment
02/08/2016

Locations

Countries of recruitment
Japan

Study participating centre
University of Kochi
2751-1 Ike, Ike campus
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Sponsor information

Organisation
Kochi Prefectural Government

Funder(s)

Funder type
Government

Funder Name
Kochi Prefectural Government Regional Development Grant 2015

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/02/2017	29/01/2019	Yes	No
Results article	results	29/08/2017	29/01/2019	Yes	No
Results article		15/05/2017	10/10/2023	Yes	No
Results article		14/10/2022	10/10/2023	Yes	No