

# The effect of consuming dulse enriched bread on markers of health

<b>Submission date</b> 11/08/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 13/10/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/05/2017	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<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

*Palmaria palmata* (*P. palmata*) is an Irish seaweed also called dulse. It has always been consumed over the years and is generally regarded as safe. There is evidence suggesting that it can have a role in promoting health but this has not been studied formally. This study will compare normal bread with bread enriched with 5g of dulse and will note any changes in markers of health.

Who can participate?

Healthy adults.

What does the study involve?

Participants are randomly allocated to one of two groups: the treatment group (bread containing 5 g *P. palmata*) or the placebo group (bread without *P. palmata*). They have to eat 1 bread roll (230 g) per day for 28 consecutive days.

What are the possible benefits and risks of participating?

This study will help understand the effects of consuming Irish seaweed on human health. No foreseeable risks are involved.

Where is the study run from?

University of Ulster in Coleraine, Northern Ireland (UK).

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

August to December 2011.

Who is funding the study?

The Irish Marine Institute and the Department of Agriculture

Who is the main contact?

Dr Emeir McSorley

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## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Emeir McSorley

**Contact details**

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**Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

**Study information****Scientific Title**

The effect of consuming *Palmaria palmata* enriched bread on inflammatory markers, antioxidant status, lipid profile and thyroid function in a randomised placebo controlled intervention trial of healthy adults

**Acronym**

SEAPALM

**Study objectives**

Consumption of *P. palmata* will favourably alter biomarkers of inflammation and other markers of health (lipid profile, thyroid function and antioxidant status)

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Research Ethics Committee of the University of Ulster; ref: REC/11/0078

**Study design**

Double-blind randomized placebo controlled human dietary intervention study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Screening

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

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

Inflammation in healthy adults - cardiovascular disease risk

**Interventions**

Palmaria palmata incorporated (5g) into bread (230g total) vs bread alone

Participants were randomly assigned to either the treatment group (bread containing 5 g P. palmata) or placebo group (bread without P. palmata) using an online randomization software ([www.randomisation.com](http://www.randomisation.com)) which was determined prior to participant recruitment. Treatment and control breads were labelled and allocated to participant ID according to the randomisation sequence output by an independent researcher not involved in the design or the analysis of the study to ensure that the study was double-blinded to both researcher and participants.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

C-reactive protein- cytokine analysis

**Secondary outcome measures**

1. Lipid profile - (cholesterol; triglycerides)
2. Thyroid function - (thyroid stimulating hormone (TSH))
3. Antioxidant status - (ferric reducing antioxidant power (FRAP))

**Overall study start date**

01/08/2011

**Completion date**

15/12/2011

## Eligibility

### Key inclusion criteria

Apparently healthy adults aged 18-65 years.

### Participant type(s)

Patient

### Age group

Adult

### Lower age limit

18 Years

### Upper age limit

65 Years

### Sex

Both

### Target number of participants

40

### Key exclusion criteria

Participants were excluded if they regularly consumed seaweed (>5 g/week), used vitamin or mineral supplements, used immune altering medication or had a history of thyroid problems.

### Date of first enrolment

01/08/2011

### Date of final enrolment

15/12/2011

## Locations

### Countries of recruitment

Northern Ireland

United Kingdom

### Study participating centre

Room W2046

Coleraine

United Kingdom

BT52 1SA

# Sponsor information

## Organisation

Department of Food, Agriculture and the Marine (Ireland)

## Sponsor details

Agriculture House, Kildare St.

Dublin

Ireland

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info@agriculture.gov.ie

## Sponsor type

Government

## Website

<http://www.nutramara.ie>

## ROR

<https://ror.org/008gjgb19>

# Funder(s)

## Funder type

Research organisation

## Funder Name

The Irish Marine Institute and the Department of Agriculture, Food and the Marine - Sea Change Strategy; Grant-Aid Agreement No. MFFRI/07/01

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration