ISRCTN34271192 https://doi.org/10.1186/ISRCTN34271192

The effect of consuming dulse enriched bread on markers of health

Submission date
11/08/2014

Recruitment status
No longer recruiting

Registration date
13/10/2014

Overall study status
Completed

Last Edited
19/05/2017

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

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

Primary study design
Interventional

Study design
Double-blind randomized placebo controlled human dietary intervention study

Study type(s)
Screening

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) 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(s)
C-reactive protein- cytokine analysis

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

Completion date
15/12/2011

Eligibility

Key inclusion criteria
Apparently healthy adults aged 18-65 years.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

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
United Kingdom

Northern Ireland

Study participating centre
Room W2046
Coleraine
United Kingdom
BT52 1SA

Sponsor information

Organisation
Department of Food, Agriculture and the Marine (Ireland)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration