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A nutritional intervention study for the evaluation of health benefits of hake consumption in a high cardiovascular risk population

Submission date 29/03/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/04/2010	**Overall study status** Completed	
Last Edited 30/04/2010	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

33UT08011

Study information

Scientific Title
The evaluation of health benefits of hake consumption in a high cardiovascular risk population: a randomised cross-over open nutritional interventional study

Study objectives
The following main hypothesis is raised: Frequent hake intake improves the individual components of the metabolic syndrome (blood pressure, lipid profile and body weight) in patients with high cardiovascular risk, and therefore yield the specific health claims for hake labelling.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Reference Review Board of the Comite Etico de Investigacion Clinica de Galicia approved on the 27th July 2008. An amendment was approved on the 31st March 2009.

Study design
Randomised cross-over open trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Can be found at http://www.ciberobn.es/webciber/index.php?option=com_phocadownload&view=category&id=6:oficina-de-proyectos&download=2:crd_proyecto33ut08011&Itemid=11 (Spanish only)

Health condition(s) or problem(s) studied
Metabolic syndrome

Interventions
Control period:
Patients are put under basic alimentary roles of a balanced diet, except for the total absence of fish intake. This will last for 8 weeks.

Intervention period:
Patients are put under basic alimentary roles of a balanced diet, but in this case they take 7 servings of white fish a week.

During the study period, all subjects will follow medical advice as well as prescribed medications by the responsible medical team attending the patients, except for the interventions described above. All the education and information given to the patients will aim to only modify fish intake, which will always be Pescanova Hake, or total absence of fish intake. For the rest of items of the diet, following the general principles of a balanced diet, patients will be told to feel free to chose foods according to their preferences as to avoid biases which could affect a short-term study.

This is a randomised cross-over open trial, with an intervention period of 8 weeks and a control one of 8 weeks. The total duration of the trial is 16 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Serum triglyceride concentrations, measured at the inclusion time and at the end of each intervention period (3 measurements altogether)

Secondary outcome measures
Measured at the inclusion time and at the end of each intervention period (3 measurements altogether):
1. Other components of the metabolic syndrome as defined by the ATP III
2. Anthropometric variables: height, weight, waist and hip circumferences
3. Biochemical markers and chronic inflammation markers
4. Adherence and feasibility of the nutritional intervention
5. Erythrocyte membrane omega-3 concentrations
6. Insulin resistance (Homeostatic Model Assessment [HOMA])

Overall study start date
25/02/2009

Completion date
01/03/2011

Eligibility

Key inclusion criteria
1. Aged between 18 and 75 years, either sex
2. Recruited in outpatients clinics of the participant centres
3. Voluntarily agree with the study protocol and give written informed consent
4. Thorough clinical history and informative meeting has been performed
5. Metabolic syndrome (primary intervention). The presence of metabolic syndrome according to 2004 ATP-III (Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults) criteria will be

evaluated. According to the latter, for the diagnosis of the metabolic syndrome, three or more of the following criteria have to be present:
5.1. Central obesity: waist circumference greater than 102 cm in men and greater than 88 cm in women
5.2. Hypertriglyceridemia: triglycerides greater than or equal to 150 mg/dL (greater than or equal to 1.7 mmol/L) or on treatment
5.3. High density lipoprotein (HDL) less than 40 mg/dL (less than 1.1 mmol/L) in men or less than 50 mg/dL (1.3 mmol/L) in women
5.4. Hypertension: systolic blood pressure greater than or equal to 130 mmHg and/or diastolic greater than or equal to 85 mmHg, or on treatment
5.5. Fasting blood glucose greater than or equal to 100 mg/dL (greater than or equal to 5.6 mmol /L) or any other carbohydrate metabolism disorder (including diabetes and glucose intolerance)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
250 Caucasians of Spanish origin

Key exclusion criteria
Those who presented any of the following after a thorough clinical history:
1. Previous allergy to fish or Anisakis infection
2. Morbid obesity (body mass index [BMI] greater than 40)
3. Chronic renal failure
4. Creatinine clearance (CrCl) greater than 30
5. Chronic psychopathology
6. Malignancy
7. Refuse to participate
8. Fibrates treatment

Date of first enrolment
25/02/2009

Date of final enrolment
01/03/2011

Locations

Countries of recruitment
Spain

Study participating centre
C/Choupana S/N
Santiago De Compostela
Spain
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Sponsor information

Organisation
Pescanova S.A. (Spain)

Sponsor details
Rua Jose Fernandez Lopez, S/N
Chapela
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36320

Sponsor type
Industry

Website
http://www.pescanova.es/

Funder(s)

Funder type
Industry

Funder Name
Pescanova S.A. (Spain)

Funder Name
Biomedical Research Center in Red-Physiopathology of Obesity and Nutrition (CIBERobn) (Spain)

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