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Crossover study of diets enriched with virgin olive oil, walnuts or almonds. Effects on lipids and other cardiovascular risk markers

Submission date
08/11/2010

Recruitment status
No longer recruiting

Registration date
14/12/2010

Overall study status
Completed

Last Edited
14/12/2010

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
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
INC0706

Study information

Scientific Title
Effects of diets enriched with virgin olive oil, walnuts or almonds on lipids and other cardiovascular risk markers: a randomised crossover study

Acronym
ONA

Study objectives
Virgin olive oil and nuts are basic components of the Mediterranean diet, a heart-healthy dietary pattern. Nuts have well known cholesterol lowering effects, while evidence is unclear for virgin olive oil. We designed a study in hypercholesterolemic patients to assess the effects on serum lipids and other intermediate markers of cardiovascular risk of replacing 40% of the fat in the background diet with virgin olive oil, walnuts or almonds. Our hypothesis is that daily intake of virgin olive oil will be associated with low density lipoprotein (LDL) cholesterol lowering to a similar extent than walnuts and almonds consumed at similar doses as percent of total energy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Review Board of the Hospital Clínic of Barcelona approved on the 21st March 2006 (ref: CEIC 3110-2006)

Study design
Randomised crossover nutrional intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions

In participants following a background Mediterranean-type isocaloric diet with similar energy, total fat and saturated fat content will be allocated to 3 random sequential periods lasting 4 weeks each in which 40% of energy (25% of fat) is replaced by virgin olive oil, walnuts or almonds.
1. Virgin olive oil is provided in 0.5 litre units sufficient to cover daily allowances of 35 to 50 g, depending on total energy requirements
2. Raw, shelled Spanish almonds (Marcona variety) provided in pre-packaged daily allowances from 50 to 75 g (almonds)
3. Spanish-grown walnuts (Serr/Chandler variety) from 40 to 65 g

No washout necessary between arms because after a dietary intervention is terminated serum lipid changes stabilise in less than 3 weeks. Duration of the study for all participants is 16 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Effects of the three diets on the serum lipid profile, with LDL cholesterol changes from baseline

Secondary outcome measures
1. Medical records, including anthropometric measurements (height, weight and waist circumference) and blood pressure at baseline and end of each diet period
2. Food, energy and nutrient intake assessed by 7-day food records at the end of each diet period
3. Plasma fatty acid proportions (as objective measure of compliance); concentrations of noncholesterol sterols, high-sensitivity C-reactive protein, homocysteine, oxidized LDL, ICAM-1, and VCAM-1; and in vitro LDL oxidizability assay to determine lag time of conjugated diene formation at baseline and end of each diet period

Overall study start date
10/01/2007

Completion date
15/12/2007

Eligibility

Key inclusion criteria
1. Asymptomatic men and women with moderate hypercholesterolemia, age 25 to 75 years (after menopause in women)
2. Serum LDL cholesterol more than 3.36 mmol/L
3. Triglycerides less than 2.82 mmol/L
4. Absence of chronic illnesses or secondary hypercholesterolemia
5. No known allergy to nuts
6. Participants can be under stable lipid-lowering drug treatment (statins or fibrates, statins at doses of no more than simvastatin 40 mg/day or equivalent)
7. Written informed consent

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Subjects on a weight-losing diet
2. Familial hypercholesterolemia
3. Established type 2 diabetes
4. Fatty food intolerance
5. Consumption of products that can influence cholesterol metabolism (other than statins and fibrates), such as resins, ezetimibe, psyllium, fish oil concentrates, soy lecithin, or phytoestrogens

Date of first enrolment
10/01/2007

Date of final enrolment
15/12/2007

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Clínic de Barcelona
Barcelona
Spain
08036

Sponsor information

Organisation
International Nut and Dried Fruit Foundation (Spain)

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Sponsor type
Research organisation

Website
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ROR
https://ror.org/030wfqt16

Funder(s)

Funder type
Research organisation

Funder Name
International Nut and Dried Fruit Foundation (Spain)

Funder Name
Spanish Ministry of Science and Innovation (Spain) - Instituto de Salud Carlos III (CIBER Fisiopatología de la Obesidad y Nutrición [CIBERobn])

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