

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

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Registration date 14/12/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/12/2010	Condition category 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
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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 nutritional intervention study

Primary study design

Interventional

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration