

Evaluation of the effect of nut consumption on energy balance, metabolic, inflammatory response and oxidation

Submission date
01/06/2006

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
19/06/2006

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
02/12/2010

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

AGL2005-03605

Study information

Scientific Title

Acronym

EFINUT

Study objectives

Regular nut consumption improves cardiovascular risk factors in metabolic syndrome patients without adverse effects on energy balance and insulin sensitivity

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by Sant Joan Hospital Ethical Committee, reference number: EFINUT-05-01-27/1proj2

Study design

Randomised controlled clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Metabolic syndrome

Interventions

Participants are randomly assigned into two equal groups:

1. Control group: low-fat diet according to American Heart Association guidelines
2. Nut group: low-fat diet according to American Heart Association guidelines with an added 30 g /day of nuts

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Peripheral inflammatory markers

Secondary outcome measures

1. Stress oxidative markers
2. Endothelial function
3. Insulin sensitivity
4. Energy balance

Overall study start date

08/01/2006

Completion date

31/12/2007

Eligibility**Key inclusion criteria**

Patients with metabolic syndrome aged between 18 and 65 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

50; male and female

Key exclusion criteria

1. Nut allergy
2. Type 2 diabetes
3. Body mass index (BMI) $>33 \text{ kg/m}^2$
4. Secondary obesity
5. Inflammatory or infectious disease
6. Anti-inflammatory or antibiotic drugs
7. Alcoholism or drug abuse
8. Recent hypocaloric diet

Date of first enrolment

08/01/2006

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

Spain

Study participating centre

C/Sant Llorenç 21

Reus

Spain

43201

Sponsor information

Organisation

Ministry of Education and Science (Ministerio de Educacion y Ciencia) (Spain)

Sponsor details

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Sponsor type

Government

Website

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Funder(s)

Funder type

Government

Funder Name

Ministry of Education and Science (Ministerio de Educacion y Ciencia)

Alternative Name(s)

Ministry of Education and Science, MEC

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Portugal

Funder Name

International Nut Council

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2010		Yes	No