

# 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

### Protocol serial number

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

**Primary study design**

Interventional

**Study design**

Randomised controlled clinical trial

**Study type(s)**

Treatment

**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(s)**

Peripheral inflammatory markers

**Key secondary outcome(s)**

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

**Completion date**

31/12/2007

**Eligibility**

**Key inclusion criteria**

Patients with metabolic syndrome aged between 18 and 65 years

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**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)

## 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

### 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?
<a href="#">Results article</a>	results	01/06/2010		Yes	No