ISRCTN36468613 https://doi.org/10.1186/ISRCTN36468613

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

Registration date
19/06/2006

Overall study status
Completed

Last Edited
02/12/2010

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jordi Salas-Salvadó

Contact details
C/Sant Llorenç 21
Reus
Spain
43201
+34 (0)97 775 93 13
jordi.salas@urv.net

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 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?
Results article	results	01/06/2010		Yes	No