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Effect of nut consumption on semen quality and functionality in healthy males

Submission date 20/05/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/05/2016	**Overall study status** Completed	
Last Edited 09/06/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Human semen quality has declined in industrialized nations, with pollution, smoking, and trends toward a Western-style diet as possible causes. Although the importance of diet to human reproductive success is clear, existing dietary recommendations primarily focus on women's reproductive health with less attention given to men. Because nuts have a considerable amount of several nutrients that are involved in male fertility, we believe that tree nut consumption added to a Western-style diet would improve semen quality and functionality. The aim of this study is to evaluate the effect of eating tree nuts on semen quality.

Who can participate?
Healthy men aged between 18 and 35

What does the study involve?
Participants are randomly allocated to one of two groups. One group continues to consume their usual diet supplemented with 60 g per day of a mixture of raw nuts. The other group continues to consume their usual diet, avoiding consumption of nuts. Blood and sperm samples are collected at the start of the study and after 14 weeks to assess sperm quality.

What are the possible benefits and risks of participating?
Participation in the study may help the participants to better understand their health. The information obtained may benefit other patients in the future and contribute to a better understanding of the effect of nut consumption on male fertility. There are no health risks involved in this study. The extraction of the blood sample can cause a burning sensation at the point where the needle is inserted and can cause a small bruise which disappears in a few days. More rarely it can cause transient dizziness.

Where is the study run from?
1. Universitat Autònoma de Barcelona (Spain)
2. Universitat Rovira i Virgili (Spain)

When is the study starting and how long is it expected to run for?
September 2015 to August 2017

Who is funding the study?
INC International Nut and Dried Fruit Council Foundation (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Effect of nut consumption on semen quality and functionality in a cohort of healthy males

Acronym
FERTINUTS

Study objectives
Because nuts have a considerable amount of several nutrients that have been implicated in the modulation of several mechanism implicated in male fertility, we hypothesize that tree nut consumption added to a Western-style diet would beneficially affect semen quality and functionality.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Comitè d'Ètica d'Investigació Clínica (Hospital Universitari Sant Joan de Reus), 29/10/2015, Ref. CEIC: 15-10-29/10aclaassN1

Study design
Randomized 14-week parallel two-group dietary intervention trial with single-blind masking of outcome assessors

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Semen quality and functionality

Interventions
Participants will be randomly assigned to one of two intervention groups for 14 weeks:
1. Continue to consume their usual diet supplemented with 60 g/day of a mixture of raw nuts.
2. Continue to consume their usual diet, avoiding consumption of nuts.

Intervention Type
Supplement

Primary outcome(s)
Improvement of sperm vitality and motility. Semen samples will be collected at baseline and the end of the intervention period. All men will be instructed to abstain for 3 days prior to providing the study specimen, with abstinence period verified by self-report on day of sample collection. Semen samples will be collected allowing analysis within 60 min of sample production. A single researcher, who was blinded as to intervention versus control group status, will perform the conventional semen analyses. For the rest of analysis aliquots of semen will be frozen at -196ºC until analysis.

Key secondary outcome(s))
Semen samples will be collected at baseline and the end of the intervention period:
1. Other conventional semen parameters
2. Plasma lipid profile, glucose and insulin concentrations
3. Serum folic acid and alpha-linolenic concentrations
4. Sperm DNA fragmentation
5. Sperm ROS evaluation
6. Sperm miRNA expression profiles
7. Sperm DNA methylation
8. Sperm chromosome stability

Completion date
31/08/2017

Eligibility

Key inclusion criteria

1. Healthy males
2. 18-35 years old
3. Reported a western-style diet

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
35 years

Sex
Male

Total final enrolment
119

Key exclusion criteria
1. Frequent consumption of nuts or a known history of allergy
2. Use of plant sterol or fish oil supplements and multivitamins, vitamin E or other antioxidant supplements
3. History of reproductive disorders or vasectomy
4. Current smokers
5. Taking antioxidant supplements or medications for chronic illness
6. Use of illegal drugs

Date of first enrolment
02/12/2015

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Spain

Study participating centre
Universitat Autònoma de Barcelona
Facultat Biociències, Edifici C, despatx C2/-120
Bellaterra (Cerdanyola del Vallès)

Spain
08193

Study participating centre
Universitat Rovira i Virgili
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Sponsor information

Organisation
INC International Nut and Dried Fruit Council Foundation (Spain)

ROR
https://ror.org/030wfqt16

Funder(s)

Funder type
Other

Funder Name
INC International Nut and Dried Fruit Council Foundation (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2018		Yes	No
Results article		04/03/2019		Yes	No
Results article		19/06/2019	20/06/2019	Yes	No
Basic results		29/11/2018	29/11/2018	No	No

Other publications	Cross-sectional and prospective analysis	29/04/2024	09/06/2025	Yes	No