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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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 -196°C until analysis.

Secondary outcome measures
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

Overall study start date
01/09/2015

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Male

Target number of participants
118 (69 in control group and 69 in intervention group)

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
C/Sant Llorenç, 21
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Sponsor information

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

Sponsor details
Carrer de la Fruita Seca 4
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Sponsor type
Other

Website
www.nutfruit.org

ROR
https://ror.org/030wfqt16

Funder(s)

Funder type
Other

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

Results and Publications

Publication and dissemination plan
Impact for the scientific community and healthcare professionals
The dissemination plan will include participation in the major scientific events in the knowledge area (nutrition and dietetics, and fertility) such as: International Congress on Nutrition (IUNS); European Congress on Nutrition (ECN); Congress of the Sociedad Española de Nutrición (SEN); European Society of Human Reproduction and Embriology (ESHRE) congress; Congress of the Asociación Española de Biología de la Reproducción (ASEBIR). Participation is also envisaged in specific congresses for primary care physicians such as the Spanish Society of Family Medicine and Community Congress (SemFYC). It is also expected to publish the results in the best journals of medicine, nutrition and dietetics, fertility, and genetics.

Impact of the research on consumers
The dissemination plan is designed for both health care and consumers, and it includes social media (participation in radio and television for the target audience in both national and international media), and Internet networks (website, Facebook, Twitter). An animated whiteboard video will be produced to target a non-scientific audience and help visualize the scientific background and results of the study.

Impact on the industry
The results will be communicated using media press releases, and the website platform and networks of the International Nut and Dried Fruits Foundation.

Intention to publish date

01/01/2018

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
Basic results		29/11/2018	29/11/2018	No	No
Results article		04/03/2019		Yes	No
Results article		19/06/2019	20/06/2019	Yes	No
Other publications	Cross-sectional and prospective analysis	29/04/2024	09/06/2025	Yes	No