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Effects of nut products on lipid metabolism in obese children

Submission date	Recruitment status	[_] Prospectively registered
24/01/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/02/2019	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/12/2024	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Obesity is a complex metabolic disease with many origins and with serious consequences for health. The rate of obesity in Spain has increased by 9% in children and young people and by 4% in adults in the last 15 years. This increase has also been observed in the Autonomous Community of the Basque Country. Although there are studies about of obesity, there is still a growing overweight and obese population in the world. It is known that diet and lifestyle are the main causes of the disease but the effect of food is not easy to measure. The excess of fat accumulated in adipose tissue leads to reduced life expectancy. Results from studies in adults have provided evidence of the beneficial effects of tree nut consumption on metabolic risk factors, obesity and metabolic syndrome (MetS), independent of demographic, lifestyle and other dietary factors. Nut products can also provide fatty acids and can therefore contribute to cell membranes. The aim of this study is to assess the effect of a diet supplemented with a combination of fatty acids from a mixture of tree nuts (walnut, Brazil nut, pecan and macadamia nuts) on obese and overweight children.

Who can participate?
Children aged 6 to 14 from the Autonomous Community of the Basque Country who are overweight or obese

What does the study involve?
Participants are randomly allocated to one of three treatment groups. In the first treatment group (control group) the children follow a traditional diet with scheduled physical activity, in the second group (nut group) the children receive a diet supplemented with a mix of tree nuts (30 g/day) and, finally, in the third group (nutraceutical group) children receive a diet with fatty acids supplements. The doctor decide the doses according to the child's requirements in the first visit to the center. Patients from all intervention groups receive dietary and physical activity recommendations. Children are studied for 6 months, and they go to the pediatrician three times (at the start of the study, at 3 months and at 6 months . Samples of blood and saliva are collected for testing. Clinical, body measurement and blood pressure data are also collected, and the participants answer some questionnaires about medical history, physical activity, eating habits, preferences and satiety.

What are the possible benefits and risks of participating?
Participants will not receive personal benefit from participating in this study. The data collected in it may lead to a greater knowledge of the disease or condition under study. Children will receive all the medical care that they may need. They will not be affected.

Where is the study run from?
OSI (Organización Sanitaria Integrada) Eskerraldea-Enkarterri-Cruces in Barakaldo (Bizkaia-Spain) and OSI-Uribe in Getxo (Bizkaia-Spain)

When is the study starting and how long is it expected to run for?
September 2017 to December 2021 (updated 15/06/2021, previously: June 2021 (updated 13/07/2020, previously: June 2020))

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

Who is the main contact?
Dr Itziar Tueros

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
1

Study information

Scientific Title
Molecular effects of nut products on cell membranes evaluated by red blood cell lipidome remodelling in obese children

Acronym
OBINUT

Study objectives
A healthy diet supplemented with an appropriate combination of fatty acids from nuts improves lipid metabolism and quality of life in childhood obesity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the research with medicines of the Basque Country (CEIM-E), Department of Health of the Basque Government-Pharmacy. Sebastian Street, nº 1. Vitoria. 01010, Tel: +34 (0)945 01 92 96; +34 (0)945 01 56 34, Email: ceic.eeaa@euskadi.eus, 18/10/2017, ref: PI2017114

Study design
Prospective randomized parallel-group open multicenter clinical trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Childhood obesity

Interventions
The study is a clinical nutrition intervention trial. A prospective, randomized, parallel-group, open and multicenter clinical trial will be conducted in 120 male and female children from 6 to 14 years (with overweight and obesity), to evaluate the effectiveness on red blood cell lipidome remodelling of a customized diet supplemented with tree nuts or fatty acid supplementation strategy, compared to conventional treatment with dietary recommendations and physical activity. Study subjects will be stratified by sex and age and subsequently randomized to follow one of three interventions of 6 months duration in a parallel design:

Control group
Usual dietary and physical activity recommendations to reduce weight and improve their health status. Participants assigned to the control diet group will receive general oral and written advise to follow a healthy diet but they will not be given individualized intervention. Regarding nuts, they will be instructed to refrain from eating nuts included in the study.

Nut group
The same physical activity recommendations as in control group but with a diet supplemented on a mix of tree nuts (15 g of walnut, 5 g Brazil nut, 5 g of pecan nut and 5 g of macadamia). Participants at baseline and after hospital visits, will be provided with 30 g of pre-packed mixed raw nuts to be eaten daily.
Nut consumption calculated to achieve contribution of ~10% of the subject's total daily energy intake and 30% and 20% of the energy from MUFAs and PUFAs in the diet respectively. Total energy intake will be calculated for obese children of 6 to 14 years around 1600-1800 Kcal.

Nutraceutical group
This group will be recommended the same physical activity as in control group but they will receive a personalized nutraceutic therapy based on: dietary recommendations + nutraceutic supplementation to restore membrane lipidomic profile. Nutraceutical type and dose administration will depend on membrane lipidomic profile at baseline compared with fatty acid ranges in healthy children (data previously acquired). Nutraceuticals from Lipinutragen or other with similar fatty acid profile from Spanish market (previously characterized in AZTI) will be administered in order to balance the SFA/MUFA. The doses administrated will be always according with daily child requirement.

Intervention Type
Supplement

Primary outcome(s)

Two blood samples of 1 ml and saliva samples are obtained while fasting at baseline and 6 months (visit 3) for the following biochemical measurements:
1. General biochemistry including total cholesterol, triglycerides, HDL - cholesterol, LDL - cholesterol, apolipoprotein A1, apolipoprotein B, SGOT and SGPT, as well as the acute phase inflammatory parameters: uric acid, C-reactive protein and homocysteine
2. Hormonal and Insulin resistance, assessed with HOMA-R levels of glycemia and insulinemia (two determinations of insulin at the beginning, mid-term and end of the study, and IGF-1 and IGF-B-3 will be required) and the interrelation among these hormones implied in the metabolism of the adipose tissue (Leptin, Adipolectin, Ghrelin)
3. Fatty acid profile of the mature erythrocyte membrane and plasma cholesteryl esters, performed in blood samples (1 ml). The samples will be sent to the CNR (Consiglio Nazionale delle Ricerche) in Bologna (Italy) to analyze the lipid profile in mature erythrocyte membrane by GC-MS. (Gas Chromatography Mass Spectrometry)

Key secondary outcome(s))
1. Anthropometric measurements, assessed for each individual following standard protocol by trained personnel. The evaluation of the pubertal stage will performed according to the Tanner's classification for each sex. Body weight, height, and waist circumferences will be measured on the same day of the first interview (at baseline) control visits (3 and 6 months)
2. Blood pressure measured with an automated device: "Critikon Dinamap -8100 "at baseline and 6 months

Measured at baseline and control visits (3 and 6 months):
3. Level of physical activity, assessed using the Physical Activity Questionnaire for Children (PAQ-C)
4. Eating behaviours, determined by the validated Dutch Eating Behaviour Questionnaire for Children (DEBQ-C) for use with Spanish children
5. Quality of life, assessed by the KIDSCREEN-10 questionnaire
6. Sleep duration and quality: parents answer the questions of the Spanish version of the Pediatric sleep questionnaire (PSQ) to report on children’s sleep duration and quality
7. Diet quality, recorded by the short Diet Quality Screener (sDQS). Parents answer the questions on their children usual dietary behaviors and Food frequency questionnaire over the previous 12 months
8. Satiety: a subjective assessment will be carried out using a 5-point Likert Scale-based questionnaire “ASTM E2299 - 13 Standard Guide for Sensory Evaluation of Products by Children and Minors”

Completion date
30/12/2021

Eligibility

Key inclusion criteria
1. Children aged 6 to 14 years
2. With overweight and obesity. Reference will be made to the body mass index (BMI), being defined as overweight when the standard deviation (SD) of the BMI ≤ 2, obesity when DE> 2 and normal weight when -2 <DS ≤ +1
3. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
14 years

Sex
All

Total final enrolment
98

Key exclusion criteria
1. Secondary sources of obesity: malformative syndromes, genetic syndromes accompanied by obesity (Beckwith, Prader-Willi, etc), drug therapies (corticosteroids, psychoactive drugs, etc), hormones alterations of any origin, alterations of the central nervous system (tumors, radiotherapy, surgery, etc)
2. Those with diabetes mellitus (except type 2)
3. Steatosis diagnosis
4. More than 5% weight loss in the 6 months prior to inclusion in the study
5. Allergic processes
6. Hypogonadism or musculoskeletal disorders
7. Transplantation
8. Subjects on antiepileptic, anxiolytic, antipsychotic, or any medication therapy that acts on the central nervous system
9. Patients under antibiotic treatment.

Date of first enrolment
01/05/2018

Date of final enrolment
30/06/2021

Locations

Countries of recruitment
Spain

Study participating centre
OSI Eskerraldea-Enkarterri-Cruces.
Plaza de Cruces, 12.

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48903

Study participating centre
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Alango street, 30.
Getxo (BIZKAIA)
Spain
48992

Sponsor information

Organisation
AZTI

Organisation
BioCruces Health Research Institute

Organisation
CNR- ISOF (Consiglio Nazionale delle Ricerche).

Funder(s)

Funder type
Other

Funder Name
International Nut and Dried Fruit Council

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes