

Effects of nut products on lipid metabolism in obese children

Submission date 24/01/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/02/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/12/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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-Urbe 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

Contact name

Dr Itziar Tueros

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Other

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

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 advice 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 measure

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)

Secondary outcome measures

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"

Overall study start date

01/09/2017

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 $-2 < DS \leq +1$
3. Written informed consent

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

14 Years

Sex

Both

Target number of participants

120

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.

Barakaldo (BIZKAIA)

Spain

48903

Study participating centre

OSI-Urbe

Alango street, 30.

Getxo (BIZKAIA)

Spain

48992

Sponsor information

Organisation

AZTI

Sponsor details

Parque Científico Tecnológico de Vizcaya, Astondo Street, Edif. 609.

Derio (Vizcaya, Spain)

Spain

48160

Sponsor type

Research organisation

Website

<https://www.azti.es/es/>

Organisation

BioCruces Health Research Institute

Sponsor details

Hospital Universitario Cruces. Plaza de Cruces, 12.

Barakaldo (Vizcaya).

Spain

48903

Sponsor type

Research organisation

Website

<https://www.biocrucesbizkaia.org/web/biocruces/inicio>

Organisation

CNR- ISOF (Consiglio Nazionale delle Ricerche).

Sponsor details

Piero Gobetti Street 101.

Bologna

Italy

40129

Sponsor type

Research organisation

Website

<https://www.isof.cnr.it/>

Funder(s)**Funder type**

Other

Funder Name

International Nut and Dried Fruit Council

Results and Publications**Publication and dissemination plan**

The study protocol with the statistical analysis plan, the chronological and economic plan will not be available online. This document was presented online to the funding agency. Results will be published in high impact scientific journals and in national and international congress on nutrition, metabolism and medical topics:

- American Journal of Clinical Nutrition
- Nutrients
- Plos One
- International Journal of Food Sciences and Nutrition
- Childhood obesity
- British Medical Journal

Intention to publish date

30/12/2025

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