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Protective role of dietary intervention rich in unsaturated fats in dyslipidemic children

Submission date
27/04/2016

Recruitment status
No longer recruiting

Registration date
10/06/2016

Overall study status
Completed

Last Edited
14/05/2018

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Regular intake of nuts, naturally rich in monounsaturated fats (MUFA) or other polyunsaturated (PUFA) sources may reduce the risk of developing cardiovascular disease (CVD) and also improve lipid profile (fats and cholesterol in the blood). People with a high level of serum lipids (that is, a lot of fat in the blood) seem to be more susceptible to oxidative stress (damage caused by free radicals) and CVD. They may therefore benefit from an increased nut or MUFA and PUFA intake. The aim of this study is to investigate the effect of hazelnuts eaten as snack or source of polyunsaturated fats (e.g. alpha-linolenic acid) on markers of oxidative stress (that is, substances that show the presence of oxidative stress), inflammation, lipid profile, dietary markers and intestinal microflora (microbiota) composition in children and adolescents with dyslipidemia (abnormal amounts of fat in the blood)

Who can participate?
Children aged 5-17 with dyslipidemia

What does the study involve?
At the beginning of the study, all participants are given dietary guidelines and are randomly allocated to one of three groups. One group eat a daily portion of hazelnuts with skin (15-30 g /Kg, based on body weight), one group eat the same amount of hazelnuts without skin and a control group receive only the dietary guidelines and are not given nuts to eat or a diet otherwise enriched with other sources of unsaturated fats. Blood samples are taken for all participants from all groups at the start of the study and then 8 weeks later for analysis.

What are the possible benefits and risks of participating?
The intake of hazelnuts as a snack is expected to improve the lipid profile and reduce the levels of oxidative stress in children and adolescents with dyslipidemia. There is are expected risks associated with the eating of the hazelnuts.

Where is the study run from?
The University of Turin and University of Milan (Italy)

When is the study starting and how long is it expected to run for?
January 2015 to December 2016

Who is funding the study?
The European Regional Development Fund

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol number: EC:CS377

Study information

Scientific Title
Effect of hazelnut or polyunsaturated fat intake on oxidative stress related markers and lipid profile in children and adolescents with primary dyslipidemia

Acronym
NO-OX Stress

Study objectives
Dyslipidemia is a major risk factor for cardiovascular disease development and it is closely associated with a decrease of antioxidant defense mechanisms. Nuts are rich sources of bioactives such as monounsaturated and polyunsaturated fatty acids, vitamins, phytosterols and polyphenols. We hypothesized that regular consumption of hazelnuts or other polyunsaturated sources (e.g. alpha-linolenic acid) could have a beneficial effect on dyslipidemia improving lipid profile and cell protection against oxidative DNA damage. Moreover, dietary interventions with polyunsaturated fats could also affect microbiota composition and inflammatory conditions eventually associated to dyslipidemia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the City of Health and Science University Hospital of Turin, 22/01/2015, ref: EC:CS377

Study design
8-week randomized controlled parallel single-blind dietary intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Familiar dyslipidemia

Interventions
The study is an 8-week randomized, controlled, parallel, single-blind dietary intervention study. Subjects receive dietary guidelines and individually randomized to the following three parallel groups of 20 subjects each:

Group 1: Children consuming hazelnuts with skin as snack (between 15-30 g per day, based on body weight)
Group 2: Children consuming hazelnuts without skin as snack (between 15-30 g per day, based on body weight)
Group 3: Children who do not consume nuts (or children consuming other sources of unsaturated fats)

At the beginning and at the end of the intervention (t= 8 weeks), blood and stool samples are collected and used to evaluate the oxidative stress related markers (e.g. DNA damage, oxidized LDL, PON-1 concentration, etc.), the serum lipid profile and erythrocyte membrane phospholipids composition. In addition, dietary and metabolic markers (e.g. microbiota composition, inflammatory related markers, etc.) are analysed.

Intervention Type
Other

Primary outcome measure
Endogenous oxidized DNA bases (using enzyme formamidopyrimidine-DNA glycosylase) measured by Comet assay in peripheral blood mononuclear cells at baseline (t=0) and at the end of intervention (t=8 weeks)

Secondary outcome measures
1. Changes in serum lipid profile triglycerides, total cholesterol, high density lipoprotein (HDL)-cholesterol, low density lipoprotein (LDL)-cholesterol
2. Changes in erythrocyte phospholipids composition
3. Changes in anthropometric characteristics (age, weight, height, body mass index)
4. Changes in blood pressure (diastolic and systolic blood pressure)
5. Changes in oxidized LDL and paraoxonase 1 (PON-1)
6. Changes in markers of inflammation
7. Changes in microbiota composition
All assessed at baseline and at the end of intervention (8 weeks)

Overall study start date
01/01/2015

Completion date
31/12/2016

Eligibility

Key inclusion criteria

1. Children aged 5-17 years affected by primary dyslipidemia (familiar hypercholesterolemia, familiar combined hyperlipidemia and undefined hypercholesterolemia),
2. Total cholesterol and/or triglycerides value higher than their age- and sex-specific 90th percentile
3. Body mass index (BMI) <95th percentile

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
60 children/adolescents

Key exclusion criteria
1. Secondary dyslipidemias, overweight or obesity (BMI ≥ 85th and ≥ 95th percentile, age and sex matched, respectively)
2. Children under lipid-lowering treatment (including functional foods) from the 3 months before the beginning of the study
3. History of renal, endocrine, liver disorders, or chronic diseases (i.e., immunologic, neurologic, or oncohematologic disorders)
4. Smokers
5. Use of any drugs, supplements, specific prebiotics or probiotics or medications at least one month before the beginning of the experiment.
6. Subjects with specific aversion or allergies to food under study

Date of first enrolment
01/01/2015

Date of final enrolment
31/05/2016

Locations

Countries of recruitment
Italy

Study participating centre

University of Turin (Università degli Studi di Torino)
Department of Health, Sciences and Pediatric
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Study participating centre
University of Milan (Università degli Studi di Milano)
Department of Food, Environmental and Nutritional Sciences Division of Human Nutrition
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Sponsor information

Organisation
Regione Piemonte

Sponsor details
Piazza Castello 165
Torino
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Sponsor type
Other

Website
http://www.regione.piemonte.it/industria/

Funder(s)

Funder type
Not defined

Funder Name
European Regional Development Fund

Alternative Name(s)

Europski Fond za Regionalni Razvoj, Den Europæiske Fond for Regionaludvikling, Europees Fonds voor Regionale Ontwikkeling, Euroopa Regionaalarengu Fond, Fonds Européen de Développement Régional, Europäischer Fonds für regionale Entwicklung, Európai Regionális Fejlesztési Alap, Fondo Europeo di Sviluppo Regionale, Eiropas Reģionālās attīstības fonds, Europos Regionines Pletros Fondas, Europejski Fundusz Rozwoju Regionalnego, Fundo Europeu de Desenvolvimento Regional, Fondul European de Dezvoltare Regională, Európsky Fond Regionálneho Rozvoja, Fondo Europeo de Desarrollo Regional, Европейски фонд за регионално развитие, Evropský fond pro regionální rozvoj, Ευρωπαϊκό Ταμείο Περιφερειακής Ανάπτυξης, Il-Fond Ewropew għall-Iżvilupp Reġjonali, Evropski sklad za regionalni razvoj, Euroopan aluekehitysrahasto, Europeiska regionala utvecklingsfonden, ERDF, FEDER, EFRE, ΕΦΡΡ, EFRR, EFRU, ERFi, ETΠA, FEDER, FESR, ERAF, ERPF, ERFA, L-FEŻR, EFRO, EFRR, FEDR, ESRR, EAKR, Eruf

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2018		Yes	No
Results article	results	01/08/2018		Yes	No