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

Submission date	Recruitment status	Prospectively registered	
27/04/2016	No longer recruiting	☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
10/06/2016	Completed	[X] Results	
Last Edited	Condition category	Individual participant data	
14/05/2018	Nutritional. Metabolic. Endocrine		

#### 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?

1. Prof. Patrizia Riso (scientific)
patrizia.riso@unimi.it

2. Prof. Ornella Guardamagna (scientific)
ornella.guardamagna@unito.it

# Contact information

#### Type(s)

Scientific

#### Contact name

Prof Patrizia Riso

#### **ORCID ID**

https://orcid.org/0000-0002-9204-7257

#### Contact details

Università degli Studi di Milano, Via Celoria 2 Milano Italy 20133 +39 (0)250 316 726 patrizia.riso@unimi.it

#### Type(s)

Scientific

#### Contact name

Prof Ornella Guardamagna

#### Contact details

Università degli Studi di Torino, Piazza Polonia 94 Torino Italy 10126 +39 (0)113 135 243 ornella.guardamagna@unito.it

# Additional identifiers

#### Protocol serial number

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

# Study type(s)

Quality of life

# 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(s)

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)

#### Key secondary outcome(s))

- 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)

#### 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

#### Healthy volunteers allowed

No

#### Age group

Child

#### Lower age limit

5 years

#### Upper age limit

#### Sex

All

#### Key exclusion criteria

- 1. Secondary dyslipidemias, overweight or obesity (BMI  $\geq$  85th and  $\geq$  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 Piazza Polonia 94 Torino Italy 10126

#### Study participating centre

#### University of Milan (Università degli Studi di Milano)

Department of Food, Environmental and Nutritional Sciences Division of Human Nutrition Via Celoria 2 Milano Italy

20133

# Sponsor information

#### Organisation

Regione Piemonte

# Funder(s)

## Funder type

Not defined

#### Funder Name

European Regional Development Fund

#### Alternative Name(s)

Fondo Europeo de Desarrollo Regional, Europäischer Fonds für regionale Entwicklung, Европейски фонд за регионално развитие, Evropský fond pro regionální rozvoj, Fundo Europeu de Desenvolvimento Regional, ERDF, FEDER, EFRE, EФPP, EFRR

#### Funding Body Type

Government organisation

## Funding Body Subtype

National government

Location

# **Results and Publications**

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
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes