

# Effects of fish oil and phytosterols on the lipid profile of children

**Submission date**  
11/11/2010

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
18/02/2011

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
15/07/2013

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
Protocol v090907

## Study information

**Scientific Title**

The influence of daily nutritional supplementation with a product comprising a combination of omega-3 fish oils and phytosterols on the levels of blood lipids in hypercholesteremic children and adolescents

**Study objectives**

Supplementation with omega-3 fish oil and phytosterols will favourably modulate lipid profile and some parameters of oxidative stress

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics Board of Medical School, Comenius University in Bratislava approved on the 24th of September 2007

**Study design**

Exploratory study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Hypercholesterolemia

**Interventions**

Daily administration of supplement comprising of omega-3 fish oil (1000mg EPA/DHA) and phytosterol esters (1300mg) for a period of 4 months

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Blood lipid profile

Blood samples were collected at weeks 0, 8 and 16 weeks.

**Key secondary outcome(s)**

1. Markers of oxidative stress

2. Antioxidant status

Blood samples were collected at weeks 0, 8 and 16 weeks.

**Completion date**

31/08/2009

# Eligibility

## Key inclusion criteria

1. Participants of either sex, aged 12-19 years
2. Parental/guardian written informed consent and completed confidential health status to be obtained for all children participating

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Child

## Lower age limit

12 years

## Upper age limit

19 years

## Sex

All

## Key exclusion criteria

1. Participants whose parents are unable/unwilling to give written informed consent
2. Participants who are not prepared to provide blood samples as required
3. Participants who are receiving lipid lowering drugs
4. Participants already involved in dietary control

## Date of first enrolment

01/10/2007

## Date of final enrolment

31/08/2009

# Locations

## Countries of recruitment

Slovakia

## Study participating centre

Institute of Medical Chemistry, Biochemistry and Clinical Biochemistry

Bratislava

Slovakia

813 72

# Sponsor information

## Organisation

Obsidian Research Ltd (UK)

## Funder(s)

### Funder type

Government

### Funder Name

Welsh Assembly Government (UK) - SMART Technology Exploitation Programme

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	08/01/2013		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes