

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

<b>Submission date</b> 11/11/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 18/02/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/07/2013	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use contact details below to request a Parental information sheet

## 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 measure**

Blood lipid profile

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

**Secondary outcome measures**

1. Markers of oxidative stress

2. Antioxidant status

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

**Overall study start date**

01/10/2007

**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

**Age group**

Child

**Lower age limit**

12 Years

**Upper age limit**

19 Years

**Sex**

Both

**Target number of participants**

30

**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)

### **Sponsor details**

c/o Dr Sue Plummer

Unit 2 Christchurch Road

Baglan Industrial Park

Port Talbot

United Kingdom

SA12 7BZ

### **Sponsor type**

Industry

### **Website**

<http://www.obsidianresearch.co.uk>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

Welsh Assembly Government (UK) - SMART Technology Exploitation Programme

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## 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