

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

Submission date 11/11/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/02/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/07/2013	Condition category 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

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?
Results article	results	08/01/2013		Yes	No