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

Submission date	Recruitment status	[_] Prospectively registered
11/11/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/02/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/07/2013	Nutritional, Metabolic, Endocrine	

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