ISRCTN89549017 https://doi.org/10.1186/ISRCTN89549017

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

Contact name
Prof Zdenka Durackova

Contact details
Institute of Medical Chemistry, Biochemistry and Clinical Biochemistry
Medical School
Comenius University
Sasinkova 2
Bratislava
Slovakia
813 72
+421 (0)2 59357416
zdenka.durackova@fmed.uniba.sk

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. 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

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?
Results article	results	08/01/2013		Yes	No