Clinical trial results:
A randomised control trial of omega-3 fatty acid on platelet and endothelial function in patients with peripheral arterial disease

Summary

EudraCT number	2005-001332-69
Trial protocol	GB
Global end of trial date	31 July 2007

Results information

Result version number	v1 (current)
This version publication date	19 August 2018
First version publication date	19 August 2018

Trial information

Trial identification

Sponsor protocol code	PG/04/100/17637

Additional study identifiers

ISRCTN number	ISRCTN54802970
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University of Aberdeen
Sponsor organisation address	Research & Innovation, Polwarth Building, Foresterhill, , Aberdeen, United Kingdom,
Public contact	Dr E Rattray, University of Aberdeen , 01224 551123, researchgovernance@abdn.ac.uk
Scientific contact	Dr Shona Fielding, University of Aberdeen, 01224 551123, researchgovernance@abdn.ac.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 January 2008
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 July 2007
Global end of trial reached?	Yes
Global end of trial date	31 July 2007
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

In patients with peripheral arterial disease, to assess the effects of omega-3 fatty acids on
1) platelet function
2) markers of endothelial activation

Protection of trial subjects:

Ethical approval was obtained from the local research ethics committee and written informed consent was obtained from each patient.

Background therapy:

150 patients who were receiving aspirin and statin therapy were recruited into a randomised cross-over double blind study involving 6 week supplementation with OMACOR fish oil versus placebo. A 12 week washout period occurred between treatments.

Evidence for comparator:

Placebo - an 80:20 blend of palm and soya bean oils, which closely match that of the average adult UK diet (British Nutrition Foundation, 1992).

Actual start date of recruitment	01 August 2005
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 150
Worldwide total number of subjects	150
EEA total number of subjects	150

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0

Adolescents (12-17 years)	0
Adults (18-64 years)	51
From 65 to 84 years	97
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

150 consecutive patients with history of stable IC & clinical findings of peripheral vascular disease were recruited over 2 year period. Patients identified at claudication clinic & from clinic database. Patients co-morbidity, cardiovascular medication & ankle brachial pressure indices were documented.

Pre-assignment

Screening details:

Eligible if their ankle brachial pressure index was less that 0.8 & they were receiving statin & aspirin therapy.

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

The placebo & supplement were indistinguishable & independently packaged by the Pharmacy Dept of Glasgow Western Infirmary. Pharmacists dispensed placebo or active drug packs according to a computer generated randomisation process. The code was held by the Trial Drugs Pharmacy Dept & was only revealed to the researchers once recruitment, data collection & lab analysis were complete.

Arms

Are arms mutually exclusive?	Yes
Arm title	OMACOR

Arm description:

850-882mg Eicoapentaenoic acid Docosahexaenoic acid

Arm type	Active comparator
Investigational medicinal product name	OMACOR
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

Six weeks of OMACOR supplementation followed by 12 weeks washout followed by six weeks of placebo

Arm title	Placebo

Arm description:

80:20 blend of palm and soybean oils.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

Six weeks of placebo followed 12 week washout followed by six weeks of OMACOR supplementation.

Number of subjects in period 1	OMACOR	Placebo
Started	77	73
Completed	77	73

Baseline characteristics

Reporting groups	
Reporting group title	Overall Trial

Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	150	150	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	51	51	
From 65-84 years	97	97	
85 years and over	2	2	
Gender categorical Units: Subjects			
Female	46	46	
Male	104	104	

End points

End points reporting groups	
Reporting group title	OMACOR
Reporting group description:	
850-882mg Eicoapentaenoic acid Docosahexaenoic acid	
Reporting group title	Placebo
Reporting group description:	
80:20 blend of palm and soybean oils.	

Primary: Von Willebrand factor antigen (vWF)	
End point title	Von Willebrand factor antigen (vWF)
End point description:	
End point type	Primary
End point timeframe:	
24 weeks	

End point values	OMACOR	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	77	73		
Units: Continuous variable				
median (standard deviation)	25 (± 52)	21 (± 52)		

Statistical analyses

Statistical analysis title	Intention to treat
Statistical analysis description:	
Data was analysed on an intention to treat basis and study findings reported in line with CONSORT.	
Comparison groups	OMACOR v Placebo
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.05
Method	Mixed models analysis

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: Within 24hrs	
Assessment type	Systematic

Dictionary used	
Dictionary name	None
Dictionary version	0

Frequency threshold for reporting non-serious adverse events: 5 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No Non-serious Adverse Events were recorded.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/22296885