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Omega-3 fatty acids on platelet and endothelial function in patients with peripheral arterial disease

Submission date	Recruitment status	[_] Prospectively registered
15/10/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/10/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/08/2012	Circulatory System	

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 v1

Study information

Scientific Title
A randomised controlled trial of omega-3 fatty acids on platelet and endothelial function in patients with peripheral arterial disease

Study objectives
Omega-3 fatty acids are able to reduce the increased platelet and endothelial function that occurs in patients with peripheral arterial disease despite medical therapy and thus may prevent future cardiovascular events.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Board of the North East Of Scotland approved in June 2004 (ref: 04/0045)

Study design
Randomised double blind cross-over trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Peripheral arterial disease

Interventions
OMACOR fish oil (850 - 882 mg eicosapentaenoic acid and docosahexaenoic acid) (intervention) or placebo (an 80:20 blend of palm and soybean oils) (control). Supplementation will be for 6 weeks, with a washout period of 12 weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Omega-3 fatty acid

Primary outcome(s)
In patients with peripheral arterial disease, to assess the effects of omega-3 fatty acids on:
1. Platelet function
2. Markers of endothelial activation

Primary and secondary timepoints are measured at baseline, immediately following 6 weeks of active/placebo treatment, 12 weeks later following washout period and prior to commencing placebo/active treatment, and at the end of 6 weeks of placebo/active treatment.

Key secondary outcome(s))

In patients with peripheral arterial disease, to assess the effects of omega-3 fatty acids on markers of inflammation.

Primary and secondary timepoints are measured at baseline, immediately following 6 weeks of active/placebo treatment, 12 weeks later following washout period and prior to commencing placebo/active treatment, and at the end of 6 weeks of placebo/active treatment.

Completion date
31/07/2007

Eligibility

Key inclusion criteria
1. Able to give informed consent
2. Have an ankle brachial pressure index (ABPI) less than 0.8
3. On a statin and aspirin
4. Must be able to attend the nurse-led claudication clinic
5. Aged 35 - 90 years, either sex

Strict attention will be paid to secondary risk factor prevention as per our local guidelines. These include measures to achieve the target blood pressure (less than 140/85 mmHg), screening for diabetes, referral to smoking cessation clinic, nicotine replacement therapy and advice on exercise.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Rest pain or ulceration, liver impairment or abnormal platelet count or diabetes
2. On clopidogrel, warfarin or non-steroidal anti-inflammatory drugs

Date of first enrolment
01/08/2005

Date of final enrolment
31/07/2007

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Aberdeen
Aberdeen
United Kingdom
AB252ZN

Sponsor information

Organisation
University of Aberdeen (UK)

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (BHF) (UK) (ref: PG/04/100/17637)

Alternative Name(s)
The British Heart Foundation, the_bhf, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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	01/04/2012		Yes	No