

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Julie Brittenden

Contact details
University of Aberdeen
c/o ward 36
Aberdeen Royal Infirmary
Foresterhill
Aberdeen
United Kingdom
AB252ZN
+44 (0)1224 559 211
j.brittenden@abdn.ac.uk

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)

Primary study design

Interventional

Study design

Randomised double blind cross-over trial

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