

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

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<b>Registration date</b> 29/10/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/08/2012	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure**

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.

**Secondary outcome measures**

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.

**Overall study start date**

01/08/2005

**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

**Age group**

Adult

**Sex**

Female

**Target number of participants**

150

**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**

Scotland

United Kingdom

**Study participating centre**

**University of Aberdeen**

Aberdeen

United Kingdom

AB252ZN

## **Sponsor information**

**Organisation**

University of Aberdeen (UK)

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<http://www.abdn.ac.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\_bhf, The British Heart Foundation, BHF

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

## 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?
<a href="#">Results article</a>	results	01/04/2012		Yes	No