ISRCTN15838383 https://doi.org/10.1186/ISRCTN15838383

Fish oil Inhibition of Stenosis in Haemodialysis grafts study

Submission date	Recruitment status	[_] Prospectively registered
29/06/2004	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/07/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/05/2012	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Charmaine Lok

Contact details
The Toronto General Hospital
11 East Wing - 216
200 Elizabeth Street
Toronto, ON
Canada
M5G 2C4
+1 416 340 4140
charmaine.lok@uhn.on.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT 67812

Study information

Scientific Title

Acronym
FISH

Study objectives
Primary Question:
Will haemodialysis patients who receive oral fish oil capsule supplementation versus placebo capsule supplementation have a lower proportion of PolyTetraFluoroEthylene (PTFE) grafts without thrombosis, radiological or surgical intervention within 12 months of creation?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from local research ethics committees.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
End Stage Renal Disease (ESRD)

Interventions
Oral supplementation with four x 1 g fish oil capsules versus placebo capsule supplementation. In addition, standard guideline recommended care of haemodialysis grafts will continue to be followed.

As of 25/10/2006, the anticipated study end date has been extended to July 2009. The previous end date of this trial was 01/07/2007.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Fish oil

Primary outcome measure
The proportion of PTFE grafts with loss of native patency within 12 months

Secondary outcome measures
Secondary Endpoints:
1. The average change in Low-Density Lipoprotein (LDL) and fasting triglyceride from baseline to six months
2. The average difference in levels of Reactive Oxygen Species (ROS) (Malondialdehyde (MDA) and 3-nitrotyrosine) and C-reactive protein at baseline and six months
3. The fatty acid composition of total serum pholspholipids at baseline and six months

Tertiary endpoints (within 12 months):
Will provide information on the long term efficacy of fish oil on graft functioning and explore some of the other potential risks and benefits associated with fish oil consumption, such as its effect on bleeding and blood pressure. Rates and proportions will both be evaluated whenever possible to allow for comparison with the literature:
1. Total rate and proportion of:
1.1. Thrombosis
1.2. Radiological or surgical interventions
2. The time to:
2.1. First thrombosis
2.2. First angioplasty
3. The primary and cumulative patencies
4. The incidence of primary failure
5. Total rate and proportion of minor and major bleeding episodes. A minor bleeding episode is on that requires compression of the bleeding vessel for more than 30 minutes for it to cease without other intervention. A major bleeding episode is defined as one that requires either:
5.1. Blood transfusion
5.2. Correction using other blood products such as fresh frozen plasma
5.3. Admission into hospital to manage the bleeding episode
5.4. Admission into hospital due to complications of the bleeding episode
6. Average change in blood pressure and the number of Blood Pressure (BP) medications from baseline to six months and 12 months. BP will be taken post-dialysis in the sitting position, on three separate occasions in a week and then averaged, during the time points indicated
7. Rate and proportion of cardiac events:
7.1. Myocardial infarction
7.2. Congestive heart failure requiring hospitalisation
7.3. Cardiac related mortality
8. All cause mortality

Overall study start date
01/01/2004

Completion date
01/07/2009

Eligibility

Key inclusion criteria
1. End stage renal disease haemodialysis patients who require a graft access
2. 18 and above years of age, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
232

Key exclusion criteria
1. Acute renal failure, likely to be reversible with recovery of renal function
2. Surgical revision of a previous access e.g. a jump graft (i.e. must be a new PTFE graft)
3. Pregnancy
4. Active malignancy
5. Active major bleed within one month of enrolment (see below for definition of major bleed)
6. Malignant hypertension
7. Receiving more than two anti-platelet agents or anticoagulants i.e. use of Acetylsalicylic Acid (ASA) and coumadin is not an exclusion
8. Life expectancy less than six months
9. PTFE grafts that fail prior to and including post-operative day seven
10. Involvement in another graft trial
11. Current fish oil ingestion at the time of randomisation
12. Any known allergy to fish or fish products

Date of first enrolment
01/01/2004

Date of final enrolment
01/07/2009

Locations

Countries of recruitment
Canada

Study participating centre
The Toronto General Hospital
Toronto, ON
Canada
M5G 2C4

Sponsor information

Organisation
Canadian Institutes of Health Research (CIHR) (Canada)

Sponsor details
Room 97
160 Elgin Street
Address locator: 4809A
Ottawa, ON
Canada
K1A OW9
+1 888 603 4178
info@cihr-irsc.gc.ca

Sponsor type
Research organisation

Website
http://www.cihr-irsc.gc.ca/

ROR
https://ror.org/01gavpb45

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT 67812)

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?
Protocol article	protocol	01/11/2007		Yes	No
Results article	results	02/05/2012		Yes	No