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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

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Additional identifiers

Protocol serial number
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.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
The proportion of PTFE grafts with loss of native patency within 12 months

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
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Sponsor information

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

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

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