ISRCTN00691795 https://doi.org/10.1186/ISRCTN00691795

PISCES: Protection against Incidences of Serious Cardiovascular Events Study with daily fish oil supplementation in dialysis patients

Submission date	Recruitment status	[X] Prospectively registered
03/10/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/11/2013	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/01/2024	Circulatory System	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
In North America, more than 450,000 people with kidney failure require dialysis. Cardiovascular (CV), (heart-related) events are the main causes of illness and death. However, there are no consistently proven medical therapies to reduce serious CV events. Fish oil may improve healing which might benefit the CV system. Our overall goal is to study the effect of fish oil in reducing CV events in dialysis patients.

Who can participate?
We aim to globally enroll about 1100 men and women aged over 18 years from participating dialysis centers.

What does the study involve?
Eligible participants will be randomly assigned to receive fish oil (four capsules per day) or placebo (dummy) supplementation. For the duration of the study they will be followed closely to see if they have any effect.

What are the possible benefits and risks of participating?
There are no known risks involved in participating in this study. New knowledge gained from the results of this study could impact the care given to dialysis patients immediately. If fish oil is found to reduce serious CV events it will significantly improve patient health and may reduce CV-event-related hospitalizations.

Where is the study run from?
This study is centrally led by Dr Charmaine Lok at The University Health Network through the Toronto General Research Institute in Toronto, Ontario, Canada

When is study starting and how long is it expected to run for?
Patients will be recruited over a 5-year period. All participants will be followed for a minimum of 3.5 years. The entire study is expected to run for 10 years starting from November 2013.

Who is funding the study?
1. Heart and Stroke Foundation of Canada
2. Peter Munk Innovation Fund
3. Chronic Kidney Disease Outcomes Research Fund via private donation (Alexander Epstein)
4. Kidney CARE Network International
5. National Health and Medical Research Council (NHMRC) (Australia)

Who is the main contact?
Dr Charmaine Lok
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Study website
http://piscesrct.org

Contact information

Type(s)
Scientific

Contact name
Dr Charmaine Lok

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Protection against Incidences of Serious Cardiovascular Events Study with daily fish oil supplementation in dialysis patients

Acronym
PISCES

Study objectives
Given the exceedingly high risk of cardiovascular disease and sudden cardiac death in hemodialysis patients and the promising preliminary data on cardiovascular events from our previous FISH study, PISCES will confirm the effects of fish oil on reducing cardiovascular (CV) events in this patient population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/06/2013, University Health Network Researchs Ethics Board, ref: 12-5769-B

Study design
Multicentre blinded (participants, study personnel, healthcare providers, outcome adjudicators), randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Incident and prevalent chronic dialysis patients with or without previous cardiovascular events

Interventions
Participants will be randomised to receive either four capsules/day of a fish oil product called 40 /20EE 1000 mg capsules (Ocean Nutrition Ltd-DSM), or matching inactive placebo (identical size, shape, colour, consistency, odour and taste). Study capsules will be steam deodorized and flavoured to ensure blinding of the intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Current primary outcome measures as of 05/08/2020:
The primary outcome is a serious CV event. A serious CV event is a composite outcome of CV death and non-fatal CVD events.
1. CV death: sudden cardiac death, fatal myocardial infarction (MI) or fatal stroke
2. Non-fatal CV events: non-fatal MI, non-fatal stroke, peripheral vascular disease (PVD) requiring amputation.
The primary outcome will be measured as rate of CV events (e.g. number of events per unit time).

Previous primary outcome measures as of 05/08/2020:
The primary outcome is a serious CV event. A serious CV event is a composite outcome of CV death and non-fatal CVD events.
1. CV death: sudden cardiac death, fatal myocardial infarction (MI) or fatal stroke
2. Non-fatal CV events: non-fatal MI, non-fatal stroke, peripheral vascular disease (PVD) requiring amputation.
The primary outcome will be measured as time to first event and as a rate (e.g. number of events per unit time).

Secondary outcome measures

Current secondary outcome measures as of 05/08/2020:
1. A composite outcome that includes all-cause mortality and the non-fatal CV events from the primary outcome
2. Individual components of the primary composite outcome
3. Heart failure (HF) requiring hospitalisation and/or intubation
4. All CV-related hospitalisations and interventions
5. All-cause mortality
These will be measured as rate (e.g. number of events per unit time). and time to first event
Also, BP measurements (pre and post HD), ECGs and blood for n-3 polyunsaturated fatty acids (PUFA) levels will be obtained at pre-determined intervals for the trial duration. N-3 PUFA levels will help determine both compliance with study intervention and associations between blood levels of n-3 PUFA and study outcomes. Data will be collected for quality of life and economic analysis.

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Overall study start date

01/11/2013

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Adult (age >18 years) men and women with end-stage kidney disease (ESKD) who require chronic hemodialysis (HD) 3 or 4 times/week of duration 5 hours/session or less
2. Clinically stable (no hospitalization or emergency room [ER] visit 1 month before enrolment)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1100

Total final enrolment
1310

Key exclusion criteria
1. Reversible, acute renal failure, likely with recovery of renal function
2. Pregnancy
3. Active malignancy
4. Active major bleed within 1 month of enrolment
5. Blood pressure (BP) higher than 180/120 (malignant level)
6. Receiving more than two antiplatelet agents or anticoagulants i.e. use of ASA and coumadin is not an exclusion
7. Life expectancy of less than 6 months (i.e. palliative dialysis patients)
8. Implanted implantable cardioverter-defibrillators (ICD) or planned ICD placement within the year
9. Involvement in another drug trial
10. Current fish oil ingestion at the time of randomization
11. Any known allergy to fish or fish products
12. Unable to provide written informed consent (self or legal representative)

Date of first enrolment
06/11/2013

Date of final enrolment
01/11/2019

Locations

Countries of recruitment
Australia

Canada

Study participating centre
Toronto General Hospital
Toronto, Ontario
Canada
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Sponsor information

Organisation
Toronto General Research Institute

Sponsor details
c/o Dr. Charmaine Lok
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Sponsor type
Research organisation

ROR
https://ror.org/042xt5161

Funder(s)

Funder type
Research organisation

Funder Name
Heart and Stroke Foundation of Canada

Alternative Name(s)

Heart and Stroke Foundation, Heart & Stroke Foundation of Canada, Heart & Stroke, Fondation des maladies du cœur et de l'AVC, Fondation des Maladies du Cœur du Canada, Fondation des maladies du cœur et de l'AVC du Canada, HSFC, HSF

Funding Body Type
Government organisation

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

Location
Canada

Funder Name
Peter Munk Innovation Fund

Funder Name
Chronic Kidney Disease Outcomes Research Fund via private donation (Alexander Epstein)

Funder Name
Kidney CARE Network International

Funder Name
National Health and Medical Research Council

Alternative Name(s)
NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study may be available upon request based on institutional data sharing agreements.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		10/01/2024	11/01/2024	Yes	No