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

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

## 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 pisces88rct@gmail.com

## Study website

http://piscesrct.org

# **Contact information**

## Type(s)

Scientific

#### Contact name

Dr Charmaine Lok

#### Contact details

Toronto General Hospital 200 Elizabeth Street 8NU-844 Toronto, Ontario Canada M5G 2C4

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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).

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- 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

#### Kev 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 M5G 2C4

# Sponsor information

## Organisation

Toronto General Research Institute

## Sponsor details

c/o Dr. Charmaine Lok 200 Elizabeth Street 8NU-844 Toronto, Ontario Canada M5G 2C4

## 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