

# Removal of molecules associated with cardiovascular disease using a new dialysis membrane

<b>Submission date</b> 26/01/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 21/07/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/08/2022	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

End-stage renal disease, also called end-stage kidney disease, occurs when chronic kidney disease — the gradual loss of kidney function — reaches an advanced state. In end-stage renal disease, the kidneys are no longer able to work as they should to meet the body's needs. The kidneys filter wastes and excess fluids from the blood, which are then excreted in urine. When the kidneys lose their filtering capabilities, dangerous levels of fluid, electrolytes and wastes can build up in the body.

End stage renal disease leads to accumulation of different sized molecules and toxins. Dialysis patients routinely undergo haemodialysis (HD) treatment three times per week. Standard dialysis treatment utilizes traditional dialysis membranes which provide size specific clearance lead to accumulation of larger molecules such as Fibroblast Growth Factor-23 (FGF-23). Accumulation of FGF-23 is thought to be associated with increased risk of death in dialysis patients. A newer dialysis membrane, called medium cut-off (MCO) membrane (e.g Theranova by Baxter Healthcare), can potentially clear relatively bigger sized molecules due to bigger pore size. No data is available regarding clearance of FGF-23 on MCO membranes. The aim of this study is to investigate if the new medium cut-off membrane can remove FGF 23.

### Who can participate?

Patients aged 18 years and over with end stage renal failure on regular HD.

### What does the study involve?

Participants will be randomly allocated to receive one week monitored HD treatment with MCO membrane followed by one week monitored conventional HD or vice versa. Both options will include a three-week interval between monitored sessions during which the patients will receive conventional HD. Blood samples will be collected before and after dialysis during monitored treatment week.

### What are the possible benefits and risks of participating?

There are no immediate clinical benefits or anticipated risks of participating in this study.

Where is the study run from?  
Salford Royal, UK

When is the study starting and how long is it expected to run for?  
February 2020 to October 2022

Who is funding the study?  
1. Kidneys for Life, UK  
2. Baxter Healthcare Ltd., UK

Who is the main contact?  
Dr Dimitrios Poulikakos  
dimitrios.poulikakos@srft.nhs.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Dimitrios Poulikakos

**ORCID ID**  
<http://orcid.org/0000-0001-7987-2247>

**Contact details**  
Salford Royal  
Stott Ln  
Salford  
Manchester  
United Kingdom  
M6 8HD  
+44 (0)161 2060138  
dimitrios.poulikakos@srft.nhs.uk

## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**  
262813

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
S19REN08-S, IRAS 262813, CPMS 43129

## Study information

**Scientific Title**

Impact of medium cut-off membrane on FGF-23 level in haemodialysis patients

**Study objectives**

Despite technological advances in the field of renal replacement therapy, mortality in haemodialysis (HD) patients remains high and is predominantly due to cardiovascular disease. One of the medium-sized uraemic molecules implicated in cardiovascular disease is FGF-23, a molecule that is increased in dialysis patients and is not removed with conventional standard dialysis membranes. A new medium cut-off membrane (MCO, TheraNova, Baxter Healthcare) has a higher molecular weight cut-off than conventional membranes that facilitates removal of larger i.e. medium-sized molecules.

The study hypothesis is that FGF-23 removal with MCO membrane will be better than conventional dialysis membranes.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 18/12/2019, Health and Care Research Wales (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB; no tel. provided; [hra.approval@nhs.net](mailto:hra.approval@nhs.net)), 19/NW/0638

**Study design**

Prospective randomized case-crossover design study

**Primary study design**

Interventional

**Secondary study design**

Randomised cross over 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**

FGF 23 clearance in haemodialysis patients

**Interventions**

This study will include adult patients with renal failure who are on long term haemodialysis (HD). During this study, patients will be randomized (using sealed envelope) to one week monitored HD treatment with MCO membrane followed by one week monitored conventional HD or to receive one week monitored conventional HD followed by one week monitored MCO membrane

treatment. Both options will include a three-week interval between monitored sessions during which the patients will receive conventional HD. Blood samples will be collected before and after dialysis during monitored treatment week. Blood samples will be tested for FGF-23 levels but also for calcium, phosphate levels, Vitamin D and PTH levels which are known to affect FGF-23 levels.

Generated data will be analysed to compare clearance of FGF-23 on conventional dialysis membranes versus clearance on MCO membrane and rate of re-accumulation of FGF-23 between dialysis sessions. If the new membrane is effective in removing FGF 23 further studies should explore the impact of the new membranes on cardiovascular profiles and cardiovascular outcomes

### **Intervention Type**

Device

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Theranova by Baxter Healthcare

### **Primary outcome measure**

FGF 23 clearance measured using blood test before and after receiving dialysis for one week with each type of membrane

### **Secondary outcome measures**

Measured using blood test before and after receiving dialysis for one week with each type of membrane:

1. Stability of FGF 23 clearance
2. Rate of FGF 23 re-accumulation
3. Phosphate, calcium and urea clearance and PTH levels
4. Range of circulating proteins measured using whole proteome analysis

### **Overall study start date**

18/07/2019

### **Completion date**

28/10/2022

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18 years and over
2. End stage renal failure
3. On regular haemodialysis

### **Participant type(s)**

Patient

### **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

20

**Key exclusion criteria**

1. Lack of capacity to consent to treatment
2. Significant residual urine output (> 500 ml of urine per 24 hours)
3. Poor dialysis adequacy (urea reduction ratio < 65%)
4. Active infection
5. Active malignancy

**Date of first enrolment**

09/09/2022

**Date of final enrolment**

09/10/2022

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Salford Royal**

Salford Royal NHS Foundation Trust

Stott Ln

Salford

Manchester

United Kingdom

M6 8HD

## **Sponsor information**

**Organisation**

Salford Royal NHS Foundation Trust

**Sponsor details**

Stott Ln, Salford  
Manchester  
England  
United Kingdom  
M6 8HD  
+44 (0)161 206 7050  
GBeverley.Greenhalgh@srft.nhs.uk

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.srft.nhs.uk/>

**ROR**

<https://ror.org/019j78370>

**Funder(s)****Funder type**

Charity

**Funder Name**

Kidneys for Life

**Funder Name**

Baxter Healthcare Ltd.

**Results and Publications****Publication and dissemination plan**

After the completion of the study, the results will be presented at regional and scientific conferences and will be submitted for publication to scientific journals.

**Intention to publish date**

30/06/2023

**Individual participant data (IPD) sharing plan**

All data generated or analysed during this study will be included in the subsequent results publication

**IPD sharing plan summary**

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version 2.2	11/01/2022	27/07/2022	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No