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

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 26/01/2020 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 21/07/2022 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 12/08/2025 | Urological and Genital Diseases | |

## 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?
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# Contact information

### Type(s)
Scientific

### Contact name
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# Additional identifiers

### Integrated Research Application System (IRAS)
262813

### Central Portfolio Management System (CPMS)
43129

### Protocol serial number
S19REN08-S

# 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), 19/NW/0638

## Study design
Prospective randomized case-crossover design study

## Primary study design
Interventional

## Study type(s)
Treatment

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

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Total final enrolment
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
United Kingdom

England

### 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

### ROR
https://ror.org/019j78370

## Funder(s)

### Funder type
Charity

**Funder Name**
Kidneys for Life

**Funder Name**
Baxter Healthcare Ltd.

# Results and Publications

## 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? |
|---|---|---|---|---|---|
| Results article | | 21/04/2025 | 12/08/2025 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Protocol file | version 2.2 | 11/01/2022 | 27/07/2022 | No | No |