

# Peritoneal dialysis using icodextrin-based solutions for patients with advanced heart failure and chronic kidney disease

<b>Submission date</b> 08/01/2015	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/01/2015	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/01/2021	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Heart failure is a condition caused by the heart failing to pump enough blood around the body at the right pressure. Once patients with severe heart failure are taking the maximum tolerated dose of heart failure medication there are no other treatments available for those who still have symptoms of shortness of breath, limited mobility and poor quality of life. In studies many patients say that they would prefer treatments that improve their quality of life even at the expense of reduced length. Peritoneal dialysis involves pumping dialysis fluid into the space inside the abdomen (tummy) to draw out waste products from the blood. The aim of this study is to find out if peritoneal dialysis can be an effective treatment for patients with heart failure causing severe symptoms and reduced kidney function.

### Who can participate?

Patients with severe heart failure and chronic kidney disease, who are taking an optimal dose of heart failure medication and considered suitable for peritoneal dialysis

### What does the study involve?

Participants are randomly allocated to receive either best standard heart failure care (control group) or best standard heart failure care with peritoneal dialysis (intervention group). Participants have five study visits over a 32-week period. Depending on the visit, participants complete a range of quality of life and symptom questionnaires, a 6-minute walk distance test, blood test, 24-hour urine test, estimation of body composition and weight measurement, as well as questions about medical history and drug dosage.

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

Not provided at time of registration

### Where is the study run from?

Royal Derby Hospital (UK)

When is the study starting and how long is it expected to run for?  
March 2015 to September 2016

Who is funding the study?  
British Heart Foundation (UK)

Who is the main contact?  
Melissa Benavente  
Melissa.Benavente@nottingham.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Melissa Benavente

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
14080

## Study information

**Scientific Title**  
PD-HF: a multicentre randomised controlled trial of Peritoneal Dialysis using icodextrin-based solutions for patients with advanced Heart Failure and stage 3-4 chronic kidney disease

**Acronym**  
PD-HF

**Study objectives**  
Once patients with severe heart failure (HF) are taking the maximum tolerated dose of heart failure medication there are no other treatments available for those who still have symptoms of

shortness of breath, limited mobility and poor quality of life. In studies many patients say that they would prefer treatments that improve quality of life even at the expense of reduced length. The purpose of this study is to find out if peritoneal dialysis can be an effective treatment for patients with heart failure causing severe symptoms and reduced kidney function.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

14/EM/1174

**Study design**

Randomised; Interventional

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled 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**

Topic: Cardiovascular disease; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

**Interventions**

Participants will be randomised into receiving best standard heart failure care (control group) or best standard heart failure care with peritoneal dialysis (intervention group).

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

1. Assess the efficacy of ultrafiltration by PD
2. To assess the efficacy of ultrafiltration by PD in patients with severe HF and moderate CKD on symptoms of HF

**Secondary outcome measures**

N/A

**Overall study start date**

30/03/2015

**Completion date**

30/09/2016

**Reason abandoned (if study stopped)**

Participant recruitment issue

## Eligibility

**Key inclusion criteria**

1. Aged >18, no upper age limit
2. Severe HF (New York Heart Association grade III or IV)
3. Chronic Kidney Disease stage 34, (MDRD estimated GFR of 1660ml/min on 2 occasions >3 months apart)
4. Fluid overload resistant to diuretics\* OR hospital admission for heart failure in last 6 months
5. Left ventricular ejection fraction = 40% in the last 2 years
6. Using optimal HF medication for = 8 weeks including ACE-inhibitor OR angiotensin receptor blocker AND aldosterone antagonist AND beta-blocker unless intolerant and without dose change for = 4 Weeks.
7. Appropriately screened for revascularization and/or cardiac resynchronization therapy if clinically indicated.

\*Diuretic resistance is defined as clinical signs of fluid overload despite >120mg of furosemide /3mg bumetanide/day.

'Fluid overload' is clinically defined as at least 2 of the following:

1. Peripheral or sacral oedema
2. Jugular venous distension = 7cm
3. Radiographic pulmonary oedema or pleural effusion
4. Enlarged liver or ascites
5. Pulmonary rales, paroxysmal nocturnal dyspnoea, or orthopnoea

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 130; UK Sample Size: 130

**Total final enrolment**

10

**Key exclusion criteria**

1. Does not wish to participate
2. Mental incapacity to consent
3. CKD stage 5 (estimated GFR of < 15ml/min)
4. Normal renal excretory function (estimated GFR of >60ml.min)
5. Haemodynamically significant valvular disease amenable to surgery
6. Cardiac or renal transplantation
7. Considered by the investigator to be unsuitable for PD due to previous abdominal surgeries, peritonitis, social circumstances or other reason

**Date of first enrolment**

30/03/2015

**Date of final enrolment**

30/09/2016

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Royal Derby Hospital**

Uttoxeter Road

Derby

United Kingdom

DE22 3NE

## Sponsor information

**Organisation**

University of Nottingham (UK)

**Sponsor details**

c/o Ms. Angela Shone

Head of Research Governance

Research & Graduate Services

King's Meadow Campus

Lenton Lane

Nottingham

England

United Kingdom

NG7 2NR

**Sponsor type**

University/education

**ROR**

<https://ror.org/01ee9ar58>

## Funder(s)

**Funder type**

Charity

**Funder Name**

British Heart Foundation

**Alternative Name(s)**

the\_bhf, The British Heart Foundation, BHF

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan**

This trial was halted due to extreme difficulty with recruitment. Only 10 participants were enrolled. Due to the paucity of data the researchers do not have any plans to make the data publicly available.

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/09/2019	14/01/2021	Yes	No

