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

Submission date 08/01/2015	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 09/01/2015	**Overall study status** Stopped	
Last Edited 15/01/2021	**Condition category** Circulatory System	

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
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Contact information

Type(s)
Scientific

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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
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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?
Results article	results	01/09/2019	14/01/2021	Yes	No

HRA research summary	28/06/2023	No	No