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Role of at-home treatment of heart failure and kidney disease patients with under-the-skin injection of "furosemide" for fluid removal

Submission date
01/10/2025

Recruitment status
Recruiting

Registration date
02/12/2025

Overall study status
Ongoing

Last Edited
02/12/2025

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients with heart failure and kidney disease are at risk of fluid quickly accumulating in their lungs and limbs causing breathlessness and swelling, and often required hospital admission to receive a medication called furosemide through their veins to remove the excess fluid.
This study will see whether a different way of delivering furosemide, with the patient staying at home and being given furosemide through a pump and needle attached to the skin of the stomach, is effective at removing excess fluid and preventing them from having to come into hospital. This research is important because hospital admissions are often unpleasant experiences for patients and are associated with risks including the development of infections and injury to the kidneys.

Who can participate?
Patients aged 18 years and over with heart failure and kidney disease

What does the study involve?
The study will have who stages that will run at the same time as each other. In the first stage we will recruit participants with heart failure and kidney disease. We will teach them to recognise when they become fluid overloaded which will include monitoring for increases in weight and for the worsening of symptoms including breathlessness and swelling. We will ask participants to contact our team when they become fluid overloaded, and we will also check in on them with a phone call every 2 months.
The second stage of the trial will run at the same time as the first stage, where we will randomly be allocating the first 80 participants who have developed excess fluid into one of two different groups: one group will receive the at-home furosemide and one group will receive usual care by attending hospital via the emergency department. The at-home furosemide group will be trained on how to use the furosemide pump. The pump has a small needle going into the skin of the stomach and is worn for 5 hours a day for 5 days.

What are the possible benefits and risks of participating?
We hope that this at-home furosemide will be effective at treating excess fluid and prevent

people with heart failure and kidney disease from being admitted to hospital.
Potential burdens for the participants include education of the subcutaneous device. They will be screened to assess competence in using it, and will be given written instructions on how to use it. We will also speak to relative and care givers who may also be with the participant. The study team will also be available every day to be contacted should they have problems or questions with the device.
Other burdens may be wearing the device for 5 hours a day. The device is small enough to be worn underneath clothing, and as such the participant can perform their usual activities of daily living. Participants will be expected to perform daily measurements, including blood pressure, weight, and oxygen saturations. We will provide them with the equipment for this. Participants will have two blood tests during the 5 days and will receive a daily phone call form the team. We will go to the participants homes for the blood tests. Participants may be needle phobic, however, this will be assessed at screening. A final burden on the patients may be that they do not wish to be randomised. Participants in stage 1 will be asked if they would be willing to be randomised later if they develop fluid overload, however, it is certainly possible that people can change their mind. We will overcome this by producing an informative information sheet, clearly explain the risks and benefits of the study, and be sure to support participants who are randomised to at-home treatment.
Risks to participants may include low potassium levels or acute kidney injury form the furosemide. Furosemide would also be given had the patient gone to hospital, so this is not an excess risk, however, blood tests performed by the study team will monitor for these common complications. There is a risk of delayed presentation to hospital should the participant become unwell enough to require admission. This will be mitigated by having the clinician at the screening visit use their judgement to decide if they are well enough to be randomised. There are strict exclusion criteria including a fever, low blood pressure, low oxygen saturations, high heart rate, and low potassium. We will also educate participants and give them written information for when to attend hospital, based on certain symptoms and the aforementioned home measurements.

Where is the study run from?
St George's Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2025 to November 2028

Who is funding the study?
National Institute for Health and Care Research (UK)

Who is the main contact?
renal.researchteam@stgeorges.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1010376

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2024.0322

Study information

Scientific Title
Impact of at-home subcutaneous furosemide in heart failure patients with chronic kidney disease on prevention of hospital admission: a randomised controlled, feasibility trial

Acronym
Home CHF

Study objectives
To study if it is feasible to treat fluid overload in participants with heart failure and chronic kidney disease, at home, with new pH-neutral furosemide, delivered via a novel medical device (a furosemide infusor), compared to usual care, in a randomised controlled trial. We will be looking at the end of the study:
1. How many participants were consented to be randomised?
2. How many participants were able to complete the intervention (5 days of new pH-neutral furosemide, delivered via a novel medical device)?
3. How many of the participants were able to self-administer the device during the 5 days?

The secondary objective is to determine how effective the new drug and device are in this particular population. However, we acknowledge that our current feasibility study is not powered to answer this question. But we will be looking at:
1. How many and how much weight do participants lose during the intervention?
2. How much does the breathlessness improve?
3. How urine sodium changes during the intervention?
4. Whether participants judge their quality of life improved?

5. Would a blood test evaluating fluid overload, nTproBNP, decrease?
6. Whether there is a reduced number of hospital admission and/or deaths?
7. How easy to device is to use by our study participants?

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted

Study design
Open randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Heart failure with chronic kidney disease, with fluid overload

Interventions
The trial will be delivered in two stages. Patients recruited in stage 1 will be randomised to stage 2 if they develop fluid overload.
Stage 1 is a follow-up study of 200 patients of heart failure with stable chronic kidney disease and recent hospital admission. In stage 1 patients will be screened and consented for both stages of the trial after been provided with information on follow-up and novel drug and device therapy in stage 2. Once recruited they will have baseline data collected and followed up with regular (two-monthly) phone calls. Once they report fluid overload either during the phone call or by themselves, they will be recruited into stage two.
Stage 2 is an open label randomised controlled trial of management of fluid overload in stage 1 patients once they have developed fluid overload. Once screened with specific inclusion /exclusion criterion the eligible (stable) patients will be recruited to stage 2. Patients will be randomised at a 1:1 ratio using an online tool to either at home 5-day course of 80mg subcutaneous furosemide daily using a novel device or standard care. The standard care for most patients will be an emergency room visit and hospital admission or dose escalation with diuretics by their usual physician. The regular medications will be unchanged. The home care patients will have daily phone calls and home visits during the five days. They will also have blood tests done twice between day 2 and 5. At any time if patient becomes unwell they will be able to be attend emergency room and get admitted into hospital. The patients will self-monitor their vitals (weight, blood pressure, pulse, oxygen saturation) daily during the five days. The patients will have blood tests, breathlessness scores, quality of life score and urine sodium done at day 1 and day 6 of the second stage. The standard care patients will have their data collected from hospital records with phone calls as required.
Patients would be followed up on the following outcomes - hospitalisation and mortality will be collected from electronic records until 30 days after completion of stage 2.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
SQIN-Furosemide

Primary outcome(s)
1. Number of participants consented to be randomised at end of stage 1, measured at the end of the trial
2. Number of participants able to complete the intervention, measured at end of trial
3. How many of the participants were able to self-administer the device during the trial, measured each day during the 5-day treatment period

Key secondary outcome(s))
1. Daily weights of the participants measured daily during the 5-day treatment period
2. Breathlessness score measured daily during the 5-day treatment period
3. Urine sodium, measured twice during the 5-day treatment period
4. Quality of life, measured using the EQ-5D-5L quality of life scale, at Day 0 and Day 6 of Stage 2 of the trial
5. NTproBNP, measured using serum blood tests twice during the 5-day treatment period
6. Hospital admissions, measured at day-30 after trial completion
7. Device ease of use, measured with device usability scale each day during the 5-day treatment period

Completion date
01/11/2028

Eligibility

Key inclusion criteria
Stage 1:
1. Age ≥18 years
2. Established HF diagnosis
3. Established CKD with stable eGFR < 60 ml/min/1.73m2
4. Hospital admission within previous twelve months
5. Able to provide informed written consent
6. Is (or has a carer who is) able and willing to administer SQIN-Furosemide with SQIN infusor at home. This will be assessed using at screening using a dummy device.
7. Is (or has a carer who is) able and willing to comply with the required monitoring at-home
8. Has a suitable home environment for the administration of SQIN-Furosemide at home

Stage 2:
1. Meets inclusion criteria of stage 1
2. Weight gain of at least 5 kg from baseline weight
3. At least one sign of congestion (e.g., pitting oedema, raised jugular venous pressure, chest crepitations, pulmonary oedema on chest x-ray)
4. Established on oral loop diuretic

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Stage 1:
1. Established on renal replacement therapy
2. Presence of lung disease causing hypoxia
3. Uncontrolled tachyarrhythmia
4. On palliative care pathway
5. Pregnant (females of childbearing potential must have a negative pregnancy test within 7 days prior to treatment initiation) or breastfeeding

Stage 2:
1. Meets any exclusion criterion in stage 1
2. Systolic blood pressure <95 mmHg
3. Oxygen saturation <95%
4. Temperature ≥39ºC
5. Presence of acute kidney injury
6. Resting heart rate >100 bpm
7. New onset arrhythmia
8. Requires admission to hospital, at clinician discretion
9. Potassium <3.5 mmol/L

Date of first enrolment
01/11/2025

Date of final enrolment
01/10/2028

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
-
-
England
-

Sponsor information

Organisation
St George’s University Hospitals NHS Foundation Trust

ROR
https://ror.org/039zedc16

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon reasonable request from our scientific contact Debasish Banerjee. As there is patient data involved, it would require approvals from the appropriate governing bodies prior to release.

IPD sharing plan summary

Available on request