ISRCTN14351189 https://doi.org/10.1186/ISRCTN14351189

# The use of ultrasound to guide fluid removal during haemodialysis

**Submission date**
17/11/2023

**Recruitment status**
No longer recruiting

**Registration date**
30/11/2023

**Overall study status**
Completed

**Last Edited**
28/03/2024

**Condition category**
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Patients who have kidney failure are unable to regulate the amount of fluid in their body. Haemodialysis allows for this excess fluid to be removed. Often the amount of fluid to be removed is difficult to decide on as multiple factors are taken into consideration. The most common method involves simply weighing the patient to see if this is above their 'dry weight'. However, this method is very crude and does not take into account factors such as how well the heart is pumping or what the blood flow to the various organs is like. This study will investigate if the amount of fluid to be removed during a dialysis session can be better assessed using a simple, non-invasive ultrasound examination. It is hoped that this simple method will better help healthcare professionals decide on how best to manage fluid balance, not just in patients undergoing haemodialysis but also in other patients who are unwell in the hospital.

Who can participate?
Patients aged 18 years old and over with a medical condition called endstage kidney failure who are undergoing regular haemodialysis.

What does the study involve?
An ultrasound examination of your heart, lungs and abdomen will be performed at three-time points – before, during and after your haemodialysis session. The examination should take about 20 minutes.

The examination of your heart is called echocardiography. It allows us to see how well the heart is pumping and how much blood is moving out from it.

The ultrasound examination of your lungs allows us to see if there is a build-up of fluid in your lungs as a result of your kidney condition.

The ultrasound examination of your abdomen allows us to measure the flow within the blood vessels that lead to your heart but also the other vital organs such as the kidneys.

Information will also be collected about their vital signs and the treatment they have received from medical charts and clinical notes. All information taken will be anonymised and held in a

secure fashion. Personal identifying data will not be divulged beyond members of the research team.

What are the possible benefits and risks of participating?
There are no direct benefits to the patient from taking part. It is hoped that the information from this study will help to improve the future treatment of people with kidney failure. Rarely screening and testing can identify a condition that the patient was not previously aware of, such as an abnormality on the heart echocardiogram or kidney ultrasound. The majority of these incidental findings are harmless, however, if an abnormality is found, the patient will be informed and the abnormality will be explained. The study team will also inform the patient's GP unless specifically asked not to.

This is an observational study using ultrasound assessment during the course of a haemodialysis session, rather than testing any new therapy. Ultrasound devices have been used in research and clinical practice and have no known safety implications.

Where is the study run from?
King's College Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2022 to December 2023

WHo is funding the study?
European Society of Intensive Care Medicine (Belgium)

Who is the main contact?
Dr Adrian Wong, adrian.wong@nhs.net (UK)

# Contact information

### Type(s)
Public, Scientific, Principal investigator

### Contact name
Dr Adrian Wong

### Contact details
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS
+44 (0)20 3299 9000
adrian.wong@nhs.net

# Additional identifiers

### Integrated Research Application System (IRAS)
305720

# Study information

### Scientific Title
Assessment with clinical ultrasound of venous excess in patients undergoing renal replacement therapy (ACUVEX-RRT)

### Acronym
ACUVEX-RRT

### Study objectives
The use of a multimodal ultrasound parameter is able to track fluid removal in patients undergoing haemodialysis

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 06/05/2022, South Central - Berkshire REC (Bristol REC Centre, Temple Quay House, Bristol, BS1 6PN, United Kingdom; +44 (0)207 104 8253; berkshire.rec@hra.nhs.uk), ref: 22/SC/0110

### Primary study design
Observational

### Study design
Single-site prospective blinded observational study

### Study type(s)
Diagnostic

### Health condition(s) or problem(s) studied
End-stage renal failure

### Interventions
This is a prospective, blinded, observational study. Patients undergoing intermittent haemodialysis will be imaged using echocardiography, lung ultrasonography, femoral vein and intra-abdominal ultrasound to quantify VEXUS scores at three-time points during the dialysis session. The change in VEXUS score with fluid removal will be the primary endpoint of the study.

Potential participants for the study will be identified during routine hospital visits or inpatient admissions. Site staff will pre-screen and screen individuals using specific criteria. Screening logs will be securely stored, encrypted for confidentiality, and will include all eligible, ineligible, and declining participants. The research team will confirm the eligibility of patients meeting the criteria.

Eligible patients will be approached by a trained clinic team member, who will provide a detailed verbal explanation of the study. The discussion will allow for questions, ensuring a comprehensive understanding. Participants will be given time to reflect on the study details provided in the patient information sheet during the initial discussion.

In this study, ultrasound assessments, including transthoracic echocardiography, will be conducted using the Affiniti Ultrasound System (Philips, UK). Patient privacy will be maintained, with imaging done behind screens or curtains. Images will be de-identified and assigned random codes to minimize bias during analysis.

Echocardiography will focus on right ventricular function and volume, with parameters such as tricuspid annular plane systolic excursion (TAPSE) and peak tricuspid regurgitation velocity recorded. Lung ultrasound will assess pleural sliding, effusions, lung consolidation, and B-lines. Abdominal assessment will include measuring the inferior vena cava, portal, hepatic, splenic vein, and femoral vein using Doppler techniques.

For example, portal vein Doppler assessment will involve confirming the portal vein's position and differentiating its flow signature. Intrarenal Doppler assessment will record renal arterial resistive index. A femoral vein ultrasound will assess velocity and flow patterns. The study will record the time taken for all assessments.

### Intervention Type
Other

### Primary outcome(s)
The efficacy of a novel ultrasound score (VEXUS) in detecting changes in venous congestion during fluid removal in patients undergoing intermittent haemodialysis measured using ultrasonography, femoral vein and intra-abdominal ultrasound at three-time points during the dialysis session

### Key secondary outcome(s)
1. Changes in selected lung ultrasound parameters during fluid removal in patients undergoing intermittent haemodialysis
2. Changes in femoral vein Doppler signal during fluid removal in patients undergoing intermittent haemodialysis

Variables measured/obtained using ultrasound – left ventricular function and size (VTi, quantitative), right ventricular function and size, IVC diameter and collapsibility, hepatic vein flow profile, portal vein flow profile, VEXUS score, lung ultrasound score, femoral vein flow profile. The patient’s blood pressure and heart rate were recorded. These measures were performed at the start, middle and end of the dialysis session. We obtained the aetiology/cause of their renal failure, target dry weight from the medical records

### Completion date
31/12/2023

## Eligibility

### Key inclusion criteria
1. Aged ≥18 years old
2. Presenting for intermittent haemodialysis
3. In excess of dry weight prior to the dialysis session

### Participant type(s)
Patient

**Healthy volunteers allowed**
No

**Age group**
Mixed

**Lower age limit**
18 Years

**Sex**
All

**Key exclusion criteria**
Previous echocardiographic evidence of right heart dysfunction

**Date of first enrolment**
01/07/2022

**Date of final enrolment**
31/12/2023

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**King's College Hospital**
Denmark Hill
London
United Kingdom
SE5 9RS

# Sponsor information

**Organisation**
King's College Hospital

**ROR**
https://ror.org/044nptt90

# Funder(s)

### Funder type
Research organisation

### Funder Name
European Society of Intensive Care Medicine

### Alternative Name(s)
ESICM

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Associations and societies (private and public)

### Location
Belgium

# Results and Publications

### Individual participant data (IPD) sharing plan
The dataset generated during and/or analysed during the study will be available upon request from Dr Adrian Wong, adrian.wong@nhs.net

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 27/03/2024 | 28/03/2024 | Yes | No |
| Participant information sheet | version 2 | 11/05/2022 | 20/11/2023 | No | Yes |
| Protocol file | version 1.2 | 14/03/2022 | 20/11/2023 | No | No |