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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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
305720

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design
Single-site prospective blinded observational study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See study outputs table

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 measure
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

Secondary outcome measures
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

Overall study start date
01/02/2022

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

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
30

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
England

United Kingdom

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

Sponsor information

Organisation
King's College Hospital

Sponsor details
Denmark Hill
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England
United Kingdom
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None provided
louisa.freemantle@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.kch.nhs.uk/patients-and-visitors/getting-to-kings/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/02/2024

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?
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
Results article		27/03/2024	28/03/2024	Yes	No