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The use of ultrasound imaging to estimate fluid status to guide the treatment of patients hospitalised with heart failure

Submission date
03/07/2021

Recruitment status
No longer recruiting

Registration date
31/08/2021

Overall study status
Completed

Last Edited
20/01/2025

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Point of care bedside ultrasound (US) has been of great use in diagnosing and monitoring patients hospitalized with heart failure. Some studies have shown that the use of lung ultrasound (LU) is a good strategy for diagnosing and monitoring the fluid status of the lung in patients with heart failure to guide diuretic treatment to facilitate recovery and to minimize the risk of hospital readmission. This study aims to find out whether LU-guided diuretic treatment reduces the length of hospital stay and 90-day re-admission rate of patients hospitalized with heart failure, in comparison with standard medical treatment.

Who can participate?
Patients aged 18 and over with decompensated heart failure

What does the study involve?
Participants will be assigned to two groups. The first group (intervention) will have bedside lung ultrasound (LU) to guide diuretic therapy and standard medical care for heart failure. The second group (control) will be assessed clinically and will be managed according to the standard medical care for heart failure only.

What are the possible benefits and risks of participating?
There is no definite risk of lung ultrasound. Imaging with ultrasound is generally safe. Patients may benefit by achieving early recovery from their illness with less need for hospital readmission in 90 days.

Where is the study run from?
Sultan Qaboos University Hospital (Oman)

When is the study starting and how long is it expected to run for?
September 2021 to March 2024

Who is funding the study?
The Research Council (Oman)

Who is the main contact?
Dr Abdullah Al-Alawi
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Lung ultrasound-guided diuretic therapy in patients hospitalized with acute decompensated heart failure: an open-label interventional clinical trial

Acronym
LUDT

Study objectives
Using B-lines to guide diuretics treatment in patients admitted with acute decompensated heart failure (ADHF) can reduce the length of hospital stay (LOS) and 90-days re-admission rate compared to standard treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/04/2021, Medical Research Ethics Committee (MREC), College of Medicine and Health Sciences, Sultan Qaboos University, ref: SQU-EC/ 355/2021

Study design
Single-centre open-label interventional controlled clinical trial following a parallel-group design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Acute decompensated heart failure

Interventions

Eligible participants who are hospitalized with ADHF in general medical wards or high dependency unit at Sultan Qaboos University Hospital (SQUH) will be invited to participate in the study after signing the informed consent.

Participants will be assigned to two groups. The first group (intervention) will have bedside lung ultrasound (LU) to guide diuretics therapy and standard medical care of ADHF. The second group (control) will be assessed clinically and will be managed according to the standard medical care of ADHF only.

The total duration of the intervention depends on the length of hospital stay and the response to the intervention. Intravenous frusemide will be adjusted targeting a urine output of 500-1000 ml/day along with the resolution of B-lines. Thiazide diuretics will be added according to the patient's symptoms if no contraindication. Once the patient is having less than three B-lines, they will be shifted to oral therapy and discharged home as appropriate. The follow-up period is 90 days from the discharge day.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome measure
Length of hospital stay (LOS) days), collected from patient’s electronic medical records, measured from the admission date until the discharge day for each patient

Secondary outcome measures
90-day re-admission rate collected from patient’s electronic medical records and a follow-up phone call at 90 days post-hospital discharge

Overall study start date
01/09/2021

Completion date
03/03/2024

Eligibility

Key inclusion criteria
1. Patient admitted with ADHF defined as dyspnoea ≥ New York Heart Association (NYHA) III, peripheral oedema, and pulmonary congestion (rales on auscultation or pulmonary vascular congestion on chest radiograph)
2. Age ≥18 years old
3. Sufficient ultrasound visualization of B-lines

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Total final enrolment
80

Key exclusion criteria
1. Chronic dialysis or having chronic kidney disease stage IV based on KDIGO criteria
2. Patients required invasive ventilation
3. Pregnant patients
4. Patients with cardiogenic shock defined as a systolic blood pressure less than 90 mmHg with end-organ hypoperfusion or requiring inotropic support
5. Concomitant acute coronary syndrome
6. Pre-existing chronic lung conditions on home oxygen or non-invasive ventilation (NIV)
7. Concomitant pneumonia
8. Severe valvular disease awaiting definitive intervention

Date of first enrolment
19/12/2021

Date of final enrolment
03/01/2024

Locations

Countries of recruitment
Oman

Study participating centre
Sultan Qaboos University Hospital
Muscat
Muscat
Oman
123

Sponsor information

Organisation
Sultan Qaboos University Hospital

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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/049xx5c95

Funder(s)

Funder type
Research council

Funder Name
The Research Council

Alternative Name(s)
TRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Oman

Results and Publications

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

Intention to publish date
30/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Abdullah M. Al Alawi (Alalawi2@squ.edu.om). Data will be available for 5 years after concluding the study. The researchers will provide data for scientific purposes only (researchers, medical journals). No data will carry any patient identifications (study codes will be used instead of patients identifications).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/10/2024	20/01/2025	Yes	No