

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/08/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/01/2025	Condition category Circulatory System	<input type="checkbox"/> 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
Alalawi2@squ.edu.om

Contact information

Type(s)
Scientific

Contact name
Dr Abdullah Al-Alawi

ORCID ID
<https://orcid.org/0000-0003-2077-7186>

Contact details
AlMubaila, Sib
Muscat
Oman
123
+968 (0)95384990
Alalawi2@squ.edu.om

Type(s)
Public

Contact name
Dr Amira Al-Badi

ORCID ID
<https://orcid.org/0000-0001-7349-8864>

Contact details
Ansab, Bawshar
Muscat
Oman
123
+968 (0)96316695
R2056@resident.omsb.org

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

03/03/2024

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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

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