

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

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<b>Registration date</b> 31/08/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/01/2025	<b>Condition category</b> 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

## 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)**

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**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?
<a href="#">Results article</a>		21/10/2024	20/01/2025	Yes	No