

Evaluation of lung ultrasound as a guiding tool for treatment adjustment in patients with heart failure admitted to hospital

Submission date 15/03/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/03/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/04/2023	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Heart failure means that the heart is unable to pump blood around the body properly. It usually occurs because the heart has become too weak or stiff.

Lung congestion (a condition caused by excess fluid in the lungs) can be evaluated with lung ultrasound (a procedure that uses high-frequency sound waves to create an image of part of the inside of the body) in patients with heart failure.

The aim of this study is to evaluate if lung ultrasound may guide heart failure treatment improving clinical outcomes (survival or the need of intravenous diuretics).

Who can participate?

Adult patients with heart failure.

What does the study involve?

Participants will receive heart failure treatment (above all diuretic treatment) guided by lung ultrasound lung congestion results or following standard of care management using physical examination. Clinical outcomes will be registered during 6 months.

What are the possible benefits and risks of participating?

The benefit is to obtain better outcomes like less mortality or less readmission rate. Risks are related to an excess of diuretic doses that may generate hypotension or renal failure.

Where is the study run from?

Sociedad Española de Medicina Interna (Spain)

When is the study starting and how long is it expected to run for?

September 2017 to March 2021

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Juan Torres-Macho, juan.torresm@salud.madrid.org

Contact information

Type(s)

Principal Investigator

Contact name

Dr Juan Torres-Macho

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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

Effect of a therapeutic strategy guided by lung ultrasound on 6-month outcomes in patients with heart failure. The EPICC trial

Acronym

EPICC

Study objectives

Pulmonary congestion (PC) is associated with an increased risk of hospitalization and death in patients with heart failure (HF). Lung ultrasound has shown to be highly sensitive for detecting PC in HF. The aim of this study is to evaluate whether lung ultrasound-guided therapy improves 6-month outcomes in patients with HF compared with conventional treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/02/2019, CEIm Hospital Universitario Puerta de Hierro (C/ Joaquín Rodrigo, 2. 28222 Majadahonda, Madrid, Spain; +34 91 191 60 00; no email provided), ref: 28981

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

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

Health condition(s) or problem(s) studied

Heart failure

Interventions

Randomized, multicenter, single-blind clinical trial in patients discharged from Internal Medicine Departments after hospitalization for decompensated HF. Randomization was performed via an online tool.

Participants were assigned 1:1 to receive treatment guided according to the presence of lung ultrasound signs of congestion (semi-quantitative evaluation of B lines and the presence of pleural effusion) versus clinical assessment of congestion (standard of care).

Participants were followed up for 6 months.

Intervention Type

Other

Primary outcome measure

Cardiovascular death, admission due to heart failure, emergency department visit due to heart failure, diuretic administration at day hospital measured using patient records at 6 months

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/09/2017

Completion date

01/03/2021

Eligibility

Key inclusion criteria

1. Age older than 18 y
2. NYHA functional class \geq II at inclusion
3. Able to attend ambulatory follow-up visits

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

152

Total final enrolment

79

Key exclusion criteria

1. Life expectancy <6 months due to a different medical condition than HF
2. Heart transplantation
3. Acute coronary syndrome
4. Recent coronary revascularization
5. Valve replacement or resynchronization in the prior 3 months
6. Pregnancy
7. Restrictive pulmonary disease or severe COPD needing continuous oxygen
8. Serum creatinine >3 mg/dl or chronic renal insufficiency in dialysis
9. Severe valve stenosis
10. Participation in another randomized study

Date of first enrolment

01/09/2018

Date of final enrolment

01/09/2020

Locations

Countries of recruitment

Spain

Study participating centre

Hospital Universitario Infanta Cristina

Parla

Spain

28981

Study participating centre

Hospital Universitario Clinico San Carlos

Madrid

Spain

28040

Study participating centre

Hospital de Zafra

Zafra

Spain

06300

Study participating centre

Hospital Vega Baja

Orihuela

Spain

03314

Study participating centre

Hospital Universitario Ramón y Cajal

Madrid

Spain

28034

Study participating centre

Hospital Lucas Augusti

Lugo

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Sponsor information

Organisation

Sociedad Española de Medicina Interna

Sponsor details

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Sponsor type

Research organisation

Website

<https://www.fesemi.org/>

ROR

<https://ror.org/0031gef94>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/05/2022

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the publication of the subsequent results

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		22/07/2019	18/03/2022	Yes	No
Results article	results	22/08/2022	05/04/2023	Yes	No