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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

Registration date
21/03/2022

Overall study status
Completed

Last Edited
05/04/2023

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Diagnostic

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(s)
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

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
01/03/2021

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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 Lucus Augusti
Lugo
Spain
27003

Sponsor information

Organisation
Sociedad Española de Medicina Interna

ROR
https://ror.org/0031gef94

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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?
Results article	results	22/08/2022	05/04/2023	Yes	No
Protocol article		22/07/2019	18/03/2022	Yes	No