

# Exhaled breath acetone as a predictor of worse prognosis in patients with advanced heart failure

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<b>Registration date</b> 05/03/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/03/2024	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study looks at a substance called exhaled breath acetone (EBA), which can indicate if someone has chronic heart failure (HF). The levels of EBA tend to be higher in people with HF, especially as their condition worsens. However, it is not clear if EBA can predict how severe someone's HF might become. The researchers want to see if EBA levels can predict whether HF patients might need intensive care, certain medical devices, a heart transplant, or if they might die while on medications called inotropes. They invited HF patients who needed inotropes to participate in the study. They used a small, portable device to collect breath samples from these patients within 24 hours of starting the inotropes. The samples were then analyzed in a lab. The study followed these patients both during their hospital stay and for six months after they left the hospital. They wanted to see if EBA levels could predict if these patients would need intensive care, specific devices, a heart transplant, or if they might pass away. They collected breath samples from 287 patients between January 2019 and August 2023 to do this research.

### Who can participate?

Patients aged between 18 and 75 years old with decompensated HF on inotropic support

### What does the study involve?

Breath collection using a previously described portable non-invasive device was performed within 24 hours of inotropes initiation and analyzed by spectrophotometry through reaction with salicylaldehyde. All participants were followed during hospitalization and 6 months after discharge to assess need for ICU; short or long-term devices; HT and overall mortality.

### What are the possible benefits and risks of participating?

Data from this study may be beneficial because a predictor biomarker of heart failure mortality biomarker would be useful to improve the treatment and identify a risk group. No risks provided at time of registration.

### Where is the study run from?

University of São Paulo (Brazil)

When is the study starting and how long is it expected to run for?  
October 2016 to March 2024

Who is funding the study?  
University of São Paulo (Brazil)

Who is the main contact?  
Daniella Dan, mottadaniella@usp.br, mottadaniella@gmail.com

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Mrs Daniella Dan

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

## Study information

### Scientific Title

EBA as a predictor of worse prognosis in patients with advanced heart failure

### Acronym

EBA-HF

### Study objectives

Exhaled breath acetone (EBA) is a predictor of worse prognosis in patients with advanced heart failure.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 11/10/2016, CAPPesq (Rua Ovídio Pires de Campos, 225, Cerqueira Cesar, São Paulo, 05.403-010, Brazil; +551126617585; cappesq.adm@hc.fm.usp.br), ref: 62098116.5.0000.0068

### Study design

Single-center prospective observational cohort study

### Primary study design

Observational

### Study type(s)

Other

### Health condition(s) or problem(s) studied

Heart failure

### Interventions

Exhaled breath acetone (EBA) is a biomarker of chronic heart failure (HF) diagnosis and prognosis. Levels of EBA are elevated among patients with HF, progressively increasing in correlation with worsening functional class and strongly correlating with clinical and laboratory signs of right-sided HF. However, the role of EBA in predicting worse prognosis in patients with severe HF has not been described yet.

This study primarily aims to investigate the value of EBA as a predictor of the composite endpoint of intensive care unit (ICU) admission, need for devices (Intra-aortic balloon pump, ECMO or left ventricular assist device), heart transplant (HT) or death in HF patients on inotropes.

Patients admitted to the ER needing inotrope use will be invited to participate in the study. Breath collection using a portable non-invasive device previously described will be performed within 24 hours of inotropes initiation and analyzed by spectrophotometry through reaction with salicylaldehyde the Institutional Ethics Committee approved the study (CAAE: 62098116.5.0000.0068).

The secondary outcomes evaluate intensive care unit (ICU) admissions, need for devices (Intra-aortic balloon pump, ECMO or left ventricular assist device), heart transplant (HT) and death in HF patients on inotropes. Between January 2019 and August 2023, breath samples were collected from 287 patients. All participants were followed during hospitalization and by 6 months after discharge to assess the need for ICU; short or long-term devices; HT and overall mortality.

### **Intervention Type**

Other

### **Primary outcome(s)**

Exhaled acetone measured in breath collected in a portable non-invasive device and analyzed using spectrophotometry after reaction with salicylaldehyde at one time point

### **Key secondary outcome(s)**

The following secondary outcomes are measured using medical records during the hospitalization to 6-months follow-up:

1. Intensive care unit (ICU) admission
2. Need for devices such as an intra-aortic balloon pump, ECMO
3. Heart transplant (HT) or left ventricular assist device (LVAD)
4. Death or in-hospital HT
5. Death or HT
6. In-hospital death
7. Overall mortality

### **Completion date**

01/03/2024

## **Eligibility**

### **Key inclusion criteria**

Patients with decompensated heart failure on inotropic support

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

18 years

### **Upper age limit**

75 years

### **Sex**

All

**Total final enrolment**

287

**Key exclusion criteria**

Not meeting the participant inclusion criteria

**Date of first enrolment**

01/01/2019

**Date of final enrolment**

31/08/2023

**Locations****Countries of recruitment**

Brazil

**Study participating centre**

**InCor - Instituto do Coração do Hospital das Clínicas da FMUSP**

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**Sponsor information****Organisation**

Universidade de São Paulo

**ROR**

<https://ror.org/036rp1748>

**Funder(s)****Funder type**

University/education

**Funder Name**

Universidade de São Paulo

**Alternative Name(s)**

University of São Paulo, USP

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Brazil

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

The dataset generated during and/or analyzed during the current study will be available upon request from Daniella Dan (mottadaniella@gmail.com). Timing for availability is to be established. A free and informed consent form was applied and signed by all participants. A REDCAP platform was used for the data.

**IPD sharing plan summary**

Available on request, Published as a supplement to the results publication