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

Submission date 10/11/2023	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 05/03/2024	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 08/03/2024	**Condition category** Circulatory System	[ ] Individual participant data [ ] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
4417/16/083

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

Secondary study design
Cohort study

Study setting(s)
Hospital, Laboratory

Study type(s)
Other

Participant information sheet
No participant information sheet available

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

Secondary outcome measures
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

Overall study start date
11/10/2016

Completion date
01/03/2024

Eligibility

Key inclusion criteria
Patients with decompensated heart failure on inotropic support

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
700

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
Av. Dr. Enéas Carvalho de Aguiar, 44 - Cerqueira César
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Sponsor information

Organisation

Universidade de São Paulo

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Sponsor type
University/education

Website
https://www5.usp.br/#english

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

Publication and dissemination plan
Planned publication in a high-impact and peer-reviewed journal

Intention to publish date

01/05/2024

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 date.

IPD sharing plan summary

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