# Perfusion index derived from a pulse oximeter to predict fluid responsiveness in patients with acute circulatory failure in the intensive care unit

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
18/05/2021	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
20/05/2021	Completed	Results
Last Edited	Condition category	Individual participant data
20/05/2021	Circulatory System	<ul><li>Record updated in last year</li></ul>

## Plain English summary of protocol

Background and study aims

A circulatory collapse (also called acute circulatory failure) is defined as a general or specific failure of the circulation. Although the mechanisms, causes and clinical syndromes are different, the effect is the same — the circulatory system fails to maintain the supply of oxygen and other nutrients to the tissues and to remove the carbon dioxide and other metabolites from them. The aim of the study is to evaluate a noninvasive device to assess which patient will benefit to treat shock with intravenous fluids.

Who can participate?

Adults over 18 years, with acute circulatory failure.

What does the study involve?

The study involves measurements of common vital signs and a change of position in the bed that will drain the blood from the legs simulating the administration of intravenous fluids. The study does not involve the administration of drugs or experimental interventions

What are the possible benefits and risks of participating? None

Where is the study run from? Hospital Angeles Tijuana (Mexico)

When is the study starting and how long is it expected to run for? March 2021 to October 2021

Who is funding the study? Investigator initiated and funded

# **Contact information**

## Type(s)

Scientific

#### Contact name

Dr Damián Gutiérrez-Zárate

#### **ORCID ID**

https://orcid.org/0000-0001-9353-4754

#### Contact details

Paseo de los Héroes No 10999, Zona Urbana Río Tijuana, Baja California Mexico 22010 6646351900 dr.quzda@gmail.com

# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

03-2021

# Study information

### Scientific Title

Changes in the plethysmographic perfusion index to detect fluid responsiveness in spontaneously ventilated patients

## **Study objectives**

Changes in perfusion index accurately detect fluid responsiveness using a passive leg raising test in spontaneously ventilated patients with acute circulatory failure.

## Ethics approval required

Old ethics approval format

# Ethics approval(s)

Approved 03/26/2021, Ethics and Research Committee of Hospital Angeles Tijuana (Operadora de Hospitales Angeles SA de CV, Paseo de los Héroes No 10999, Zona Urbana Río, Tijuana, Mexico; no telephone number provided; drclementezuniga@gmail.com), ref: none

## Study design

Prospective observational study

## Primary study design

Observational

## Study type(s)

Screening

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

Patients with acute circulatory failure

#### **Interventions**

Baseline data will be collected from all patients in a semi-fowler position (head between 30-35°). Which include demographic characteristics and hemodynamic measurements (changes in perfusion index and velocity integral time by transthoracic echocardiography). Subsequently, the passive leg elevation raising maneuver will be performed. After 2 minutes, when the maneuver produces its maximum effect on CO, another set of hemodynamic measurements will be taken. Afterward, the patient is returned to the initial semifowler position and after hemodynamic stabilization (2 minutes), the third set of hemodynamic measurements will be performed.

## Intervention Type

Behavioural

## Primary outcome(s)

Perfusion index and velocity integral time will be measure at baseline (time 0), after a passive leg-raising maneuver (time 1), and semi-fowler position after 2 minutes (time 2). (The changes of the (perfusion index) PI and (velocity integral time) VTI will be represented in relative changes:

[PI before the maneuver (time 0) - PI after the maneuver (time 1)] / PI before the maneuver (time 0)  $\times$  100

and, [VTI before the maneuver (time 0) - VTI after the maneuver (time 1)] / IVT before the maneuver (time 0) x 100 respectively. A passive leg-raising maneuver will be defined as positive when an increase in VTI greater than or equal to 15%.)

## Key secondary outcome(s))

There are no secondary outcome measures

# Completion date

31/10/2021

# **Eligibility**

Key inclusion criteria

- 1. Age greater than or equal to 18 years
- 2. With spontaneous ventilation
- 3. Patients with acute circulatory failure, defined as:
- 3.1. Hypotension (systolic blood pressure <90 mmHg and/or mean arterial pressure <65 mmHg, or drop in mean arterial pressure ≥40 mmHg from baseline), and/or
- 3.2. Use of vasopressors, associated with:
- 3.3. Signs of hypoperfusion (altered mental state, oligoanuria, lactate greater than or equal to 2 mmol/L, clinical skin changes associated with hypoperfusion)

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

#### Sex

All

## Key exclusion criteria

- 1. Presence of atrial fibrillation
- 2. Invasive mechanical ventilation in controlled modalities
- 3. Situations in which a passive leg raising maneuver is contraindicated (head trauma, deep vein thrombosis in the pelvic limbs, intra-abdominal hypertension> 12 mmHg)
- 4. Patients with a poor echocardiographic window and in whom an adequate 5-chamber apical window cannot be obtained
- 5. Patients whose echocardiogram shows aortic stenosis and insufficiency

## Date of first enrolment

01/04/2021

## Date of final enrolment

31/10/2021

# Locations

## Countries of recruitment

Mexico

# Study participating centre Hospital Angeles Tijuana

Paseo de los Heroes 10999 Zona Urbana Rio Tijuana

# Sponsor information

## Organisation

Hospital Angeles Tijuana

# Funder(s)

## Funder type

Other

## **Funder Name**

Investigator initiated and funded

# **Results and Publications**

## Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

# IPD sharing plan summary

Data sharing statement to be made available at a later date

# **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes