

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

Submission date 18/05/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/05/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/05/2021	Condition category 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

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

Who is the main contact?
Damián Gutiérrez-Zárate MD, dr.guzda@gmail.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Screening

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

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 measure

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:

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

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

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

29/03/2021

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 \geq 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

34

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

Tijuana

Mexico

22010

Sponsor information

Organisation

Hospital Angeles Tijuana

Sponsor details

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Zona Urbana Río

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+52 6646351900

servicios.clinicos.hti@saludangeles.com

Sponsor type

Hospital/treatment centre

Website

<https://www.hospitalesangeles.com/tijuana/>

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

01/04/2022

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