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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

Registration date
20/05/2021

Overall study status
Completed

Last Edited
20/05/2021

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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.guzda@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
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) x 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
Tijuana
Mexico
22010

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