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The benefits of early inotropic administration compared to refractory phase inotropic administration in pediatric patients with septic shock

Submission date
12/01/2023

Recruitment status
No longer recruiting

Registration date
26/01/2023

Overall study status
Completed

Last Edited
25/01/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Septic shock, particularly protracted or refractory shock episodes, is a significant cause of morbidity and mortality in the pediatric critical care unit. According to current guidelines, only stubborn cases have received inotrope administration in the therapy of septic shock; however, there have not been many investigations to determine whether earlier administration could improve outcomes.
Inotropic medications are drugs that affect the contractility of the heart muscle. They can be used to increase or decrease the strength of the heart's contractions.
This study compares the effects of giving epinephrine immediately after resuscitation or giving it an hour later.

Who can participate?
Pediatric patients with septic shock

What does the study involve?
The effects on septic shock will be measured by several laboratory parameters, including peripheral oxygen saturation, leukocyte count, c-reactive protein (CRP), ferritin, troponin I, and serum lactate levels.

What are the possible benefits and risks of participating?
Benefits: There is a .possible benefit of early inotrope administration
Risks: Minimal risk due to early epinephrine infusion, as the authors and attending paediatricians monitored patients strictly. Early epinephrine infusion has also been regarded as safe according to sepsis guidelines in our centre.

Where is the study run from?
Udayana University (Indonesia)

When is the study starting and how long is it expected to run for?
April 2019 to April 2021

Who is funding the study?
Udayana University (Indonesia)

Who is the main contact?
Dr Dyah Kanyawati, dyahkanyawati@unud.ac.id

Contact information

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Principal investigator

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Additional identifiers

Protocol serial number
C4 277

Study information

Scientific Title
Improvement of serum ferritin levels with inotropic administration in early phase compared to refractory phase in pediatric patients with septic shock: a preliminary randomized controlled trial study

Acronym
Early Phase Inotropic Administration in Pediatric Septic Shock (EPIASS study)

Study objectives
Early use of inotropes agent in refractory septic shock cases result in lower ferritin level especially in the first hour after administration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/05/2020, Komisi Etik Penelitan (Jalan P. Serangan Denpasar, Bali, Indonesia; +62 361244534; infofk@unud.ac.id), ref: 1034/UN14.2.2.VII.14/LT/2020

Primary study design
Interventional

Study design
Randomized controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Improvement in the outcome of pediatric patients with septic shock by early administration of inotropic

Interventions
Pediatric patients who first came to the paediatric ED in Prof. dr. IGNG Ngoerah Hospital in the study period of December 2019 until December 2020 with a diagnosis of septic shock according

to the history, physical examination, as well as a scoring system based on the diagnostic criteria for septic shock were included in the study.

Data collection proceeded only after consent was initially taken from parents. Patient's blood samples were collected (CRP levels, leukocytes, troponins, serum ferritin, lactate levels and oxygen saturation) as initial markers.

Study participants were randomly allocated into two groups: an early group who received immediate epinephrine infusion (0.05–0.3 µg/kg/min via infusion pumps through peripheral catheters and were shifted to a central line as soon as the line was established) and participants who received epinephrine infusion 1 hour after fluid resuscitation.

Patients' allocations were randomly determined to classify the study groups, the random sequence was computer generated using www.sealedenvelope.com. After a patient enrolled, the paediatric resident on duty supervision of the paediatrician on duty opened the sealed envelope and initiated the study drug according to allocations. Blood samples (CRP levels, leukocytes, troponins, serum ferritin, lactate levels and oxygen saturation) were collected again after the patient is given epinephrine infusion either in the early phase or after the refractory phase at the first, 6 and 24 hours. The paediatrician on duty made the decision to taper or increase the inotropes agent according to the patient's clinical condition. Participants were not followed after initial management and care in the ER, data were only taken according to participants' conditions in the paediatric ER.

Intervention Type
Drug

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
Epinephrine

Primary outcome(s)
Ferritin levels in blood samples measured using a ferritin test at 1, 6, and 24 hours following the administration of epinephrine

Key secondary outcome(s)
Levels in blood samples at 1, 6, and 24 hours following administration of epinephrine:
1. Leukocytes measured using a white blood cell count
2. C-Reactive Protein (CRP) measured using a CRP test
3. Troponin-I measured using a troponin test
4. Lactate measured using a lactic acid test
5. Oxygen saturation measured using a pulse oximeter

Completion date
30/04/2021

Eligibility

Key inclusion criteria

1. Pediatric patients diagnosed with septic shock and presenting to the pediatric emergency department of RS Prof Ngoerah between December 2019 and December 2020
2. Pediatric patients whose parents agree to sign the informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Total final enrolment
13

Key exclusion criteria
1. Pediatric patients with congenital diseases, such as congenital heart disease
2. Undergoing therapy for renal diseases
3. History of prematurity
4. Fluid resuscitation has been done in other healthcare facilities

Date of first enrolment
01/12/2019

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Indonesia

Study participating centre
RSUP Prof Dr. IGNG Ngoerah
Jl. Diponegoro
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Sponsor information

Organisation
Udayana University

ROR
https://ror.org/035qsg823

Funder(s)

Funder type
University/education

Funder Name
Universitas Udayana

Alternative Name(s)
Udayana University, University of Udayana, Udayana University Rectorate, UNUD

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Indonesia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current studi aare/will be available upon request from Dyah Kanyawati (email: dyahkanyawati@unud.ac.id)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			25/01/2023	No	Yes
Protocol file			25/01/2023	No	No