

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

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<b>Registration date</b> 26/01/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/01/2023	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

### Type(s)

Principal investigator

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### 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 Penelitian (Jalan P. Serangan Denpasar, Bali, Indonesia; +62 361244534; infofk@unud.ac.id), ref: 1034/UN14.2.2.VII.14/LT/2020

### Study design

Randomized controlled study

### Primary study design

Interventional

### 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](http://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

Denpasar

Indonesia

80361

# 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 study are/will be available upon request from Dyah Kanyawati (email: [dyahkanyawati@unud.ac.id](mailto:dyahkanyawati@unud.ac.id))

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			25/01/2023	No	Yes
<a href="#">Protocol file</a>			25/01/2023	No	No