Septic Shock Management Guided by Ultrasound: A Randomized Control Trial (SEPTICUS Trial)

INFORMED CONSENT

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EXPLANATION FOR FOLLOWING THE RESEARCH

1. I am Saptadi Yuliarto, a Pediatric Emergency Consultant and Pediatric Intensive Therapy, hereby ask you to volunteer in the research entitled
2. The aim of this study was to determine that the administration of fluid resuscitation according to the USSM protocol can provide a different outcome through signs of improvement of shock and the incidence of tissue edema (lung and hepatomegaly). This protocol can be of benefit to early recognition of signs of tissue edema in children. This study is very useful to assist in the management of shock conditions in pediatric sepsis patients, with monitoring of hemodynamic conditions is expected to accelerate the improvement of the condition, monitor children better and prevent side effects.
3. Fluid administration procedure by giving crystalloid fluid therapy (Ringer Lactate / Ringer Acetate) in the amount of 10-20 ml/kg perbolus. Fluid administration techniques use Disconnect-Reconnect (DRT) and Push-Pull (PPT) techniques and hemodynamic monitoring using advanced hemodynamic monitoring tools USCOM and ultrasound. This method may cause discomfort or fear in the child, but you don't need to worry because it is done by professional medical personnel and is carried out in conjunction with an evaluation of the improvement of the shock condition and if there are side effects then immediate management will be given. All maintenance costs caused as a result of the research activities will be borne by the researcher.
4. The advantage that you get in your participation is that we can find out the improvement of septic shock conditions and immediately intervene early to prevent tissue edema. Patients will receive good monitoring, accelerate the patient's condition and prevent the occurrence of side effects as quickly as possible.
5. Based on references, a side effect of fluid resuscitation is tissue edema. However, the dose of fluid resuscitation is according to international standards and does not exceed the dose so that no side effects are expected. Therapy of these side effects is the provision of medical / non-medicamentous which will be accounted for by the researcher. If these symptoms appear in the patient, fluid administration will be stopped immediately for immediate treatment. The flow if symptoms of tissue edema appear, namely: clinical symptoms appear tightness, swelling of the eyelids, then the administration of fluids will be immediately stopped and recorded in the side effect monitoring book. There will be an emergency evaluation of the patient soon. Patients will receive medical or non-medical management in accordance with the side effect conditions that arise. Patients will be

evaluated whether they require further observation or observation in the intensive care unit or in the emergency department

6. If you do not agree with this method then you may not participate in this research at all, and it will not affect hospital services for you
7. Your name and identity will remain confidential
8. This decision was made by the patient after receiving an explanation from the researcher.
9. A token of gratitude to the subject in the form of a doll key chain.
10. Additional examination costs are borne by the researcher.

RESEARCHER

(dr. Saptadi Yuliarto Sp.A(K), M.Kes)

STATEMENT OF CONSENT TO
PARTICIPATE IN THE RESEARCH

I, the undersigned, declare that:

1. I have understood what is stated in the explanation sheet above and it has been explained by the researcher
2. I hereby declare that I am voluntarily willing/unwilling *) to participate as one of the research subjects entitled

Malang, …… .., 2021

Researcher	Who makes the statement
(dr. Saptadi Yuliarto Sp.A(K), M.Kes)	(…….....)
Witness 1	Witness 2
(.....)	(.....)

*) Cross one out