

# The application of contrast-enhanced ultrasound to acute kidney injury after sepsis

<b>Submission date</b> 14/12/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/01/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/07/2020	<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

Sepsis is an infection that can cause organs to fail. Sepsis can cause Acute Kidney Injury (AKI), then causing sepsis shock. It is reported that sepsis patients with mild AKI will increase their mortality. Therefore, for clinicians and patients, how to effectively predict the incidence of AKI associated with sepsis is a major issue. CEUS is an injection of contrast agents in the blood to observe tissue perfusion (the passage of fluids), allowing clinicians to see if the kidneys have been impacted. From Sepsis related AKI, is one of the main causes of low perfusion of renal tissue. Therefore, the aim of this study is to examine if CEUS can be used to observe and predict the occurrence of sepsis related AKI and can improve the survival rate of patients with sepsis.

### Who can participate?

Adults aged 18 and older who have sepsis.

### What does the study involve?

Participants are allocated to one of two groups. Those in the first group are AKI as determined by AKIN criteria. Those in the second group are the non-AKI group based on the AKIN criteria. Participants undergo CEUS injections and are followed up with ultrasound scans and contrast-enhanced ultrasound examination on the day of injections, one day, three days and seven days after the injection.

### What are the possible benefits and risks of participating?

There are no risks or benefits with participating.

### Where is the study run from?

This study is being run by the emergency intensive care unit (EICU) of the Emergency Department Sir Run Run Shaw Hospital affiliated to the Zhejiang University (China).

### When is the study starting and how long is it expected to run for?

August 2017 to September 2019

### Who is funding the study?

Zhejiang Provincial Natural Science Foundation of China (China)

Who is the main contact?  
Dr Zhongheng Zhang (Public)

## Contact information

**Type(s)**  
Public

**Contact name**  
Dr Zhongheng Zhang

**Contact details**  
Department of Emergency Medicine  
Sir Run Run Shaw Hospital  
Zhejiang University School of Medicine  
Hangzhou  
China  
310000

## Additional identifiers

**Protocol serial number**  
20171212

## Study information

**Scientific Title**  
The utility of contrast-enhanced ultrasound for the prediction of acute kidney injury after sepsis

**Study objectives**  
CEUS is a method in which an injection of a contrast agent into a blood vessel in order to develop a microvascular approach to observe tissue perfusion. The pathogenesis of sepsis related AKI is mainly the hypoperfusion of renal tissue. Therefore, CEUS can be used to observe and predict the occurrence of sepsis related AKI.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Ethics committee of Sir Run Run Shaw Hospital, an affiliated hospital of Zhejiang University, Medical College, 02/08/2017, ref:2016C91401

**Study design**  
This is a prospective observational study. Patients diagnosed with sepsis were included in this study and divided into AKI and non-AKI groups based on the AKIN criteria. Conventional ultrasound scan and contrast-enhanced ultrasound examination are measured at 0 day, 1 day, 3 day, and 7 day after admitted to the emergency intensive care unit (EICU).

**Primary study design**

Observational

### **Study type(s)**

Prevention

### **Health condition(s) or problem(s) studied**

Sepsis, severe sepsis and septic shock

### **Interventions**

This study is observational and uses CEUS to dynamically detect the changes in renal microcirculation perfusion in the AKI and non-AKI groups. If the problem about renal microcirculation perfusion was found through CEUS, they would be treated as soon as possible.

Patients diagnosed with sepsis are included in this study and divided into AKI and non-AKI groups based on the AKIN criteria. Conventional ultrasound scan and contrast-enhanced ultrasound examination are measured at day 0, 1 day, 3 day, and 7 day after admitted to the emergency intensive care unit (EICU).

### **Intervention Type**

Other

### **Primary outcome(s)**

Contrast-enhanced ultrasound examination results will be measured using the the time-intensity curve (TIC) at day 0, 1, 3 and 7 following EICU entry.

### **Key secondary outcome(s)**

The flow sheet of intensive care unit, routine hematology and biochemistry profile will be measured manually every day. The patient's survival status will be measured using hospital outpatient visits or telephone interviews at 1 months, 3 months after discharge.

### **Completion date**

30/09/2019

## **Eligibility**

### **Key inclusion criteria**

1. Patients with sepsis, severe sepsis and septic shock can be admitted for the enrollment if they were over 18 years old
2. Sepsis is defined as an acute change in total SOFA score  $\geq 2$  points as a result of anti-inflammatory function. The definition of septic shock is sepsis with persistent hypotension, requiring vasopressors for the maintenance of mean arterial pressure (MAP)  $\geq 65$  mmHg and with serum lactate level  $> 2$  mmol/L (18mg/dL), inspite of the administration of adequate volume.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. EICU stay less than 24 hours or refuse related salvage treatment
2. Patients with chronic kidney disease and long-term hemodialysis
3. Critically ill patient who had already started RRT due to AKI before EICU admission
4. Past history of kidney transplantation
5. AKI caused by obstructive causes

**Date of first enrolment**

11/01/2018

**Date of final enrolment**

30/06/2019

## Locations

**Countries of recruitment**

China

**Study participating centre**

**Sir Run Run Shaw Hospital affiliated to Zhejiang University**

The emergency intensive care unit (EICU) of the Emergency Department

Hangzhou

China

310000

## Sponsor information

**Organisation**

Zhejiang Provincial Natural Science Foundation of China

**ROR**

<https://ror.org/04aqat463>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Zhejiang Provincial Natural Science Foundation of China

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. Website: <http://www.medresman.org/login.aspx>. To receive the details of participant data, contact [liuning8905@163.com](mailto:liuning8905@163.com) for the account and password. This website will be available for all the time. There were no comments on data anonymisation, any ethical or legal restrictions, and any additional comments.

### IPD sharing plan summary

Stored in repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	29/07/2019	27/07/2020	Yes	No