

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

Submission date 14/12/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/01/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/07/2020	Condition category 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
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310000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet: liuning8905@163.com

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/08/2017

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 ≥ 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) ≥ 65 mmHg and with serum lactate level > 2 mmol/L (18mg/dL), in spite of the administration of adequate volume.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200 patients

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

Sponsor details

Sir Run Run Shaw Hospital
Zhejiang University School of Medicine
Hangzhou
China
310000

Sponsor type

Government

ROR

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

Funder(s)

Funder type

Government

Funder Name

Zhejiang Provincial Natural Science Foundation of China

Results and Publications

Publication and dissemination plan

We planned publication in a high-impact peer reviewed journal and the publish date will be planned around one year after our overall trial end date.

Intention to publish date

30/09/2020

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 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?
Protocol article	protocol	29/07/2019	27/07/2020	Yes	No