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

Submission date
14/12/2017

Recruitment status
No longer recruiting

Registration date
11/01/2018

Overall study status
Completed

Last Edited
27/07/2020

Condition category
Infections and Infestations

[X] 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
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 affliated 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
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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 an 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 affliated hospital of Zhejiang University, Medical College, 02/08/2017, ref:2016C91401

Primary study design
Observational

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).

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 ≥ 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), 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 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