

TCTR ID : TCTR20210213001

Overall Recruitment Status : Recruiting

OTHER ID :

Retrospective registration
This protocol was registered after enrollment of the first participant.

Tracking Information

First Submitted Date : 10 February 2021
First Posted Date : 13 February 2021
Last Update Posted Date : 13 February 2021

Title

Public Title : Mortality of Single Induction Dose of Etomidate versus Ketamine for Emergency Intubation in Sepsis Patients: A Randomized Study
Acronym : RSI in Sepsis
Scientific Title : Mortality of Single Induction Dose of Etomidate versus Ketamine for Emergency Intubation in Sepsis Patients: A Randomized Study
Sponsor ID/ IRB ID/ EC ID : MTU-EC-EM-0-224/61
Registration Site : Thai Clinical Trials Registry
URL : <https://www.thaiclinicaltrials.org/show/TCTR20210213001>
Secondary ID : No Secondary ID

Ethics Review

1. Board Approval : Submitted, approved
Approval Number : 056/2562
Date of Approval : 12 February 2019
Board Name : The Human Research Ethics Committee of Thammasat University No.1 (Faculty of Medicine)
Board Affiliation : Thammasat University, Thailand
Board Contact : Business Phone : 6629269704 Ext. No Data
Business Email : ec.medtu@gmail.com
Business Address : 95 Moo 8, Paholyotin Road, Auphur Klongluang, Pathumthani, Thailand 12120

Sponsor

Source(s) of Monetary or Material Supports : Thammasat University
Study Primary Sponsor : Thammasat University
Responsible Party : Name/Official Title : Assoc.Prof. Winchana Srivilaithon
Organization : Thammasat University
Phone : 6629269999 Ext. No Data
Email : medtu_research@yahoo.com
Study Secondary Sponsor : No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis : Sepsis is a common disease in emergency department (ED). Septic patients often require emergency intubation by using rapid-sequence intubation (RSI). However, there are limit evidences support the best induction agent in septic patients. This study aims to compare the mortality rate after single induction dose of etomidate versus ketamine for intubating septic patients.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied : Sepsis is a common disease in emergency department (ED). Septic patients often require emergency intubation by using rapid-sequence intubation (RSI)
Keywords : intubated sepsis patients ketamine etomidate mortality Rapid sequence intubation

Eligibility

Inclusion Criteria : 1. Evidence of infection (fever, sign or symptom of infection. unexplained hypotension, or blood culture positive) and

2. qSOFA at least 2 points or delta SOFA at least 2 points and
3. Needed emergency intubation in emergency department

Gender : Both

Age Limit : Minimum : 18 Years Maximum : N/A (No limit)

- Exclusion Criteria :
1. Crash airway
 2. Have do-not-attempt resuscitation order
 3. Severe uncontrolled hypertension (over 180/110 mmHg)
 4. Congestive heart failure
 5. Evidence of increase intracranial pressure
 6. Evidence of adrenal insufficiency

Accept Healthy Volunteers : No

Status

Overall Recruitment Status : Recruiting

Key Trial Dates	Study Start Date (First enrollment) : 12 February 2019	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 12 February 2021	Indicate Type : Anticipated
	Study Completion Date : 12 March 2021	Indicate Type : Anticipated

Design

Study Type : Interventional

Primary Purpose : Treatment

Study Phase : Phase 3

Intervention Model : Parallel

Number of Arms : 2

Masking : Masked Masked Role : Allocation concealment, Subject, Investigator, Outcome Assessor, Statistician

Allocation : Randomized

Control : Active

Study Endpoint Classification : Safety Study

Sample size

Planned sample size : 260

Intervention Arm 1

Intervention name : Etomidate

Intervention Type : Active Comparator

Intervention Classification : Drug

Intervention Description : Etomidate 0.2-0.3 mg per kg IV stat before intubation

Intervention Arm 2

Intervention name : Ketamine

Intervention Type : Active Comparator

Intervention Classification : Drug

Intervention Description : Ketamine 1 mg per kg IV stat before intubation

Outcome

Primary Outcome

1. Outcome Name : Mortality

Metric / Method of measurement : Mortality rate

Time point : at 24 hours, 7 days, and 28 days after intervention

Secondary Outcome

1. Outcome Name : Vasopressor

Metric / Method of measurement : Vasopressor rate

Time point : at 1 hours after intervention

Location

Section A : Central Contact

Central Contact	First Name : Winchana	Middle Name :	Last Name : Srivilaithon
	Degree : MD	Phone : 66863669260 Ext. : No Data	Email : winchanas@gmail.com
Central Contact Backup	First Name : Winchana	Middle Name :	Lastname : Srivilaithon
	Degree : MD	Phone : 66988899561 Ext. : No Data	Email : winchanas@hotmail.com

Section B Facility Information and Contact

1. Site Name : Thammasat University hospital
City : Pathumthani State/Province : Pathumthani Postal Code : 12121
Country : Thailand Recruitment Status : Recruiting

Facility Contact First Name : Winchana Middle Name : Last Name : Srivilaithon
Degree : MD Phone : 66863669260 Ext. : No Data Email : winchanas@gmail.com

Facility Contact Backup First Name : Winchana Middle Name : Last Name : Srivilaithon
Degree : MD Phone : 66988899561 Ext. : No Data Email : winchanas@hotmail.com

Investigator Name First Name : Winchana Middle Name : Last Name : Srivilaithon
Degree : MD Role : Principal Investigator

Section C : Contact for Public Queries (Responsible Person)

First Name : Winchana Middle Name : Last Name : Srivilaithon
Degree : MD Phone : 66863669260 Ext. : No Data Email : winchanas@gmail.com
Postal Address : 558/384
State/Province : Bangkok Postal Code : 10310
Country : Thailand Official Role : Study Principal Investigator
Organization Affiliation : Thammasat University

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Winchana Middle Name : Last Name : Srivilaithon
Degree : MD Phone : 66863669260 Ext. : No Data Email : winchanas@gmail.com
Postal Address : 558/384
State/Province : Bangkok Postal Code : 10310
Country : Thailand Official Role : Study Principal Investigator
Organization Affiliation : Thammasat University

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : No
Reason : Prohibited from rules and regulations

Publication from this study

MEDLINE Identifier : No Data
URL link to full text publication : No Data
