TCTR ID : TCTR20160808002

OTHER ID :

Overall Recruitment Status : Completed **(Has Results)**

Prospective registration
This protocol was registered before enrollment of the first participant.

Tracking Information

First Submitted Date :	04 August 2016
First Posted Date :	08 August 2016
Last Update Posted Date :	10 November 2021

Title

Public Title :	Effects of dynamic parameter-guided versus static parameter-guided fluid resuscitation on mortality in patients with sepsis and/or septic shock in Thammasat University Hospital
Acronym :	No Data
Scientific Title :	Clinical outcomes of dynamic IVC-guided versus static CVP-guided fluid resuscitation in patients with sepsis and/or septic shock in Thammasat University Hospital: A randomized controlled trial
Sponsor ID/ IRB ID/ EC ID :	MTU-EC-IM-2-102/59
Registration Site :	Thai Clinical Trials Registry
URL :	https://www.thaiclinicaltrials.org/show/TCTR20160808002
Secondary ID :	No Secondary ID

Ethics Review

1. Board Approval :	Submitted, approved
Approval Number :	MTU-EC-IM-2-102/59
Date of Approval :	15 July 2016
Board Name :	Human Research Ethics Committee of Thammasat University No.1 (Faculty of Medicine)
Board Affiliation :	Faculty of Medicine, Thammasat University
Board Contact :	Business Phone : 6629269704 Ext. No Data
	Business Email : EC.MEDTU@gmail.com
	Business Address : 99/209 Moo 18 Paholyotin Road, Klongnueng, Klongluang, Pathum Thani 12120

Sponsor

Source(s) of Monetary or Material Supports :	Thammasat University
Study Primary Sponsor :	Thammasat University
Responsible Party :	Name/Official Title : Thiti Sricharoenchai
	Organization : Division of Pulmonary and Critical Care Medicine, Department of Internal Medicine, Faculty of Medicine, Thammasat University
	Phone : 6629269794 Ext. No Data
	Email : thiti_x@tu.ac.th
Study Secondary Sponsor :	No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis :	This is a single-blind randomized controlled trial investigating whether the effects of dynamic parameter-guided fluid resuscitation in septic patients on mortality; and other outcomes (targets of resuscitation, shock duration, amount of fluid and vasopressor administration, invasive respiratory support and length of stay) are different from those of static central venous pressure (CVP)-guided fluid resuscitation.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied :	sepsis septic shock
Keywords :	sepsis inferior vena cava diameter variation static central venous pressure ultrasound fluid resuscitation mortality

Eligibility

Inclusion Criteria :	All of the following characteristics:

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1. age of 15 years old or more
2. Quick SOFA of 2 or more
3. SOFA of 2 or more
4. unstable hemodynamics (SBP <90 mmHg or decrease in SBP >40 mmHg from baseline or MAP <70 mmHg for 6 hours or less
5. fluid resuscitation required for unstable hemodynamics

Gender : Both

Age Limit : Minimum : 15 Years Maximum : 100 Years

Exclusion Criteria : One of the following characteristics:
1. pregnant woman
2. cardiogenic pulmonary edema
3. inability to lie down (e.g., scoliosis)
4. limited measurement of IVC diameter by ultrasound (e.g., abdominal mass compressing IVC)
5. difficulty in performing central venous catheterization or CVP measurement (e.g., superior vena cava obstruction)

Accept Healthy Volunteers : No

Status

Overall Recruitment Status : Completed

Key Trial Dates		
	Study Start Date (First enrollment) : 10 August 2016	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 22 April 2020	Indicate Type : Actual
	Study Completion Date : 31 March 2021	Indicate Type : Actual

Design

Study Type : Interventional

Primary Purpose : Treatment

Study Phase : Phase 2

Intervention Model : Parallel

Number of Arms : 2

Masking : Open Label

Allocation : Randomized

Control : No treatment / Standard of care

Study Endpoint Classification : Safety/Efficacy Study

Sample size

Planned sample size : 122

Actual sample size at study completion : 123

Intervantion Arm 1

Intervention name : static central venous pressure-guided fluid resuscitation

Intervention Type : Active Comparator

Intervention Classification : Procedure/Surgery

Intervention Description : Central venous pressure (CVP) of less than 8 mmHg, and 8 mmHg or more were considered as fluid responsiveness, and fluid non-responsiveness, respectively.

Intervantion Arm 2

Intervention name : dynamic inferior vena cava-guided fluid resuscitation

Intervention Type : Experimental

Intervention Classification : Procedure/Surgery

Intervention Description : In dynamic inferior vena cava (IVC) group, the patients were classified as follows: 1. Mechanically ventilated patients were measured for IVC distensibility index with 18% or more, and less than 18% considered as fluid responsiveness, and fluid non-responsiveness, respectively. 2. Spontaneously breathing patients were measured for IVC collapsibility index with 50% or more, and less than 50% considered as fluid responsiveness, and fluid non-responsiveness, respectively.

Outcome

Primary Outcome

1. Outcome Name : 30-day mortality

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Metric / Method of measurement : survival status

Time point : 30 days

Secondary Outcome

1. Outcome Name : macrovascular targets

Metric / Method of measurement : mean arterial pressure MAP of 65 mmHg or more, urine output of 0.5 milliliter(s) per kilogram per hour or more

Time point : 6 hours

2. Outcome Name : microvascular targets ScvO2 of 70% or more, lactate clearance of 10% or more 6 hours

Metric / Method of measurement : ScvO2 of 70% or more, lactate clearance of 10% or more

Time point : 6 hours

3. Outcome Name : duration of shock

Metric / Method of measurement : time from treatment initiation to MAP of 65 mmHg or more and adequate tissue perfusion

Time point : time at MAP of 65 mmHg or more and adequate tissue perfusion

4. Outcome Name : total volume of fluid administration

Metric / Method of measurement : total volume of fluid administration and total volume of fluid administration per kilogram of body weight

Time point : 72 hours

5. Outcome Name : accumulated dose of norepinephrine

Metric / Method of measurement : accumulated dose of norepinephrine and accumulated dose of norepinephrine per kilogram of body weight

Time point : time at norepinephrine cessation

6. Outcome Name : endotracheal intubation with mechanical ventilation

Metric / Method of measurement : endotracheal intubation and initiation of mechanical ventilation

Time point : time at endotracheal intubation and initiation of mechanical ventilation

7. Outcome Name : duration of mechanical ventilation

Metric / Method of measurement : time from initiation to cessation of mechanical ventilation

Time point : time at cessation of mechanical ventilation

8. Outcome Name : hospital length of stay

Metric / Method of measurement : time from hospital admission to hospital discharge

Time point : time at discharge from hospital

9. Outcome Name : intensive care unit length of stay

Metric / Method of measurement : time from intensive care unit admission to intensive care unit discharge

Time point : time at discharge from intensive care unit

Location

Section A : Central Contact

Central Contact	First Name : Thiti	Middle Name :	Last Name : Sricharoenchai
	Degree : M.D.	Phone : 6629269794 Ext. : No Data	Email : thiti_x@tu.ac.th
Central Contact Backup	First Name : Pannarat	Middle Name :	Lastname : Saisirivechakun
	Degree : M.D.	Phone : 6629269794 Ext. : No Data	Email : pannaratsaisirivechakun@gmail.com

Section B Facility Information and Contact

1. Site Name : Thammasat University Hospital

	City : Pathum Thani	State/Province : Not applicable	Postal Code : 12120
	Country : Thailand	Recruitment Status : Completed	
Facility Contact	First Name : Thiti	Middle Name :	Last Name : Sricharoenchai
	Degree : M.D.	Phone : 6629269794 Ext. : No Data	Email : thiti_x@tu.ac.th
Facility Contact Backup	First Name : Pannarat	Middle Name :	Last Name : Saisirivechakun
	Degree : M.D.	Phone : 6629269794 Ext. : No Data	Email : pannaratsaisirivechakun@gmail.com
Investigator Name	First Name : Thiti	Middle Name :	Last Name : Sricharoenchai
	Degree : M.D.	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

	First Name : Thiti	Middle Name :	Last Name : Sricharoenchai

Degree : M.D. Phone : 6629269794 Ext. : No Data Email : thiti_x@tu.ac.th
Postal Address : 99/209 Moo 18 Paholyotin Road, Klongnueng, Klongluang
State/Province : Pathum Thani Postal Code : 12120
Country : Thailand Official Role : Study Principal Investigator
Organization Affiliation : Faculty of Medicine, Thammasat University

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Thiti Middle Name : Last Name : Sricharoenchai
Degree : M.D. Phone : 6629269794 Ext. : No Data Email : thiti_x@tu.ac.th
Postal Address : 99/209 Moo 18 Paholyotin Road, Klongnueng, Klongluang
State/Province : Pathum Thani Postal Code : 12120
Country : Thailand Official Role : Study Principal Investigator
Organization Affiliation : Faculty of Medicine, Thammasat University

Summary Results

Date of posting of results summaries : 19 October 2021

Date of first journal publication of results : Not yet published

Baseline Characteristics : The baseline characteristics of all patients, dynamic inferior vena cava (IVC) and static central venous pressure (CVP) were as follows: median (IQR) age of 72 (61-80), 74 (64-81) and 68.5 (55-78) years, male of 53.7%, 52.5% and 54.8%, median (IQR) SOFA of 7 (5-7), 7 (4-9) and 8 (6-11), median (IQR) APACHE-II score of 23 (20-29), 23 (17-28) and 24 (20-30), respectively. All baseline characteristics and severity of sepsis, including comorbidities and sources of infection were comparable between the two intervention groups.

Participant Flow : A total of 995 patients with sepsis were screened for eligibility, and 124 patients were included. After stratification by APACHE II of less than 25 or 25 or more, 62 patients were randomized into each intervention group. One patient in the dynamic IVC group withdrew after randomization because of discomfort for data collection, leaving 123 patients included in the analysis. One additional patient in the static CVP group was excluded from analysis for the 30-day mortality because they were referred to another hospital and their survival status could not be tracked.

Adverse events : The rate of fluid overload between dynamic IVC vs. static CVP groups were not different (9.8% vs. 17.7%, p-value 0.204). Relative risk for fluid overload of dynamic IVC group vs. static CVP group was 0.6 (95%CI 0.2-1.4, p 0.214). Pneumothorax was not found in either intervention group.

Outcome Measures : The outcomes between dynamic IVC vs. static CVP groups were as follows: 30-day mortality rate (34.4% vs. 45.9%, p-value 0.196), achievement of at least 1 macrovascular target in 6 hours (95.1% vs. 95.2%, p-value 0.984), achievement of at least 1 microvascular target in 6 hours (94.2% vs. 85.5%, p-value 0.130), mean (+/-SD) fluid volume in 72 hours (8,327.3 (+/-2,968.7) vs. 8,929.4 (+/-2,822.5) mL, p-value 0.381, and 154.3 (+/-61.8) vs. 155.5 (+/-58.4) mL/kg, p-value 0.934), median duration (IQR) of shock (0.8 (0.4-1.6) vs. 1.5 (1.1-3.1) days, p-value 0.001), median (IQR) accumulated dose of norepinephrine (NE) (6.8 (3.9-17.8) vs. 16.1 (7.6-53.6) mg, p-value 0.008 and 0.1 (0.1-0.3) vs. 0.3 (0.1-0.8) mg/kg, p-value 0.017), endotracheal intubation with mechanical ventilation (MV) (54.1% vs. 67.7%, p-value 0.121), median (IQR) duration of MV (5 (3-27) vs. 16 (4-44 days, p-value 0.190), median (IQR) hospital length of stay (LOS) (16.5 (6.5-36.5) vs. 23 (11-51) days, p-value 0.097) and median (IQR) intensive care unit LOS (7.5 (5.5-30) vs. 20.5 (8-49) days, p-value 0.291). Relative risk for 30-day mortality of dynamic IVC group was 0.8 (95%CI 0.5-1.2, p 0.201), compared with static CVP group.

Brief Summary of Results : Dynamic IVC-guided fluid resuscitation does not affect mortality of patients with sepsis. However, it may reduce duration of shock and accumulated dose of NE, compared with static CVP guided fluid resuscitation.

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : Yes

Plan description : The datasets used and/or analyzed in this study are available from the corresponding author on reasonable request.

Publication from this study

MEDLINE Identifier : No Data

URL link to full text publication : No Data