

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparing the effect of albumin and crystalloid serum as resuscitation fluid in survival of patients with severe sepsis shock

Protocol summary

Summary

The aim of present study, is to compare the effect of albumin and crystalloid serum as resuscitation fluid in survival of patients with severe sepsis shock. In a single center clinical trial study with control group, 20 patients with severe septic shock whom admitted to surgery intensive care unit (ICU) of Imam Reza Hospital of Tabriz University of Medical Sciences, will include the study. Inclusion criteria are age between 12 to 75 years old, and patients with severe septic shock. Exclusion criteria is contraindication for albumin infusion. Patients with using random numbers table will allocate in two groups of intervention and control group. In control group patients will receive standard treatment for septic shock including crystalloid serum, antibiotics, vasopressor, and heart-lung support, and also proper surgical interventions, and in intervention group in addition to all these treatments 100 CC albumin 20% will add on per liter of crystalloid serum of patients will. This type of fluid resuscitation will continue until death or discharge from the ICU. Patients will follow up for 28 days. The primary outcome of present study is patient survival and organ failure is as secondary variable of present study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040316473N5**

Registration date: **2016-07-06, 1395/04/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-06, 1395/04/16

Registrant information

Name

Farzad Kakaei

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences.

Expected recruitment start date

2016-06-04, 1395/03/15

Expected recruitment end date

2016-07-05, 1395/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of albumin and crystalloid serum as resuscitation fluid in survival of patients with severe sepsis shock

Public title

Comparing the effect of albumin and crystalloid serum as resuscitation fluid in survival of patients with severe sepsis shock

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 12 to 75 years old; existence of at least two symptoms of SIRS syndrome

(body temperature above 38 or below 36 ° C.; respiratory rate above 20 or PCO2 less than 32 or need for mechanical ventilation; heart rate more than 90, leukocytosis above 12,000 or leukopenia less than 4000 or band cells in peripheral blood smear); existence of a focal infection based on positive culture or existence of an obvious infected area such as peritonitis or pneumonia; need to resuscitation with fluid (tachycardia; systolic blood pressure less than 100 mm Hg or mean arterial pressure less than 75 mm Hg; urine volume less than 0.5 cc/kg/hr; need for vasopressor to maintain blood pressure; central venous pressure (CVP) less than 10 mm Hg). Exclusion criteria: brain death patients; patients undergoing plasmapheresis; contraindications of albumin infusion; heart failure or pulmonary failure or renal failure; transplant patients; patients with burns; heart surgery at 3 recent months.

Age

From **12 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Daneshgah Street, Tabriz.

City

Tabriz

Postal code**Approval date**

2015-10-26, 1394/08/04

Ethics committee reference number

TBZMED.REC.1394.658

Health conditions studied**1****Description of health condition studied**

Septic shock

ICD-10 code

R57.2

ICD-10 code description

Septic shock

Primary outcomes**1****Description**

Survival of patients

Timepoint

Daily for 28 days

Method of measurement

clinical examination

Secondary outcomes**1****Description**

Renal failure

Timepoint

Daily for 28 days

Method of measurement

Creatinine level

Intervention groups**1****Description**

In intervention group: fluid resuscitation with crystalloid serum plus 100 cc albumin 20% per 1 liter of crystalloid serum.

Category

Treatment - Drugs

2**Description**

In control group: fluid resuscitation only with crystalloid serum.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Farzad Kakaei

Street address

Imam Reza Hospital, Daneshgah street, Tabriz.

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department Of Surgery, Tabriz University of Medical Sciences.

Full name of responsible person

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Position

Associate Professor of General Surgery

Other areas of specialty/work

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University Of Medical Sciences.

Full name of responsible person

Dr Hasan Soleimanpour

Street address

Deputy of Research and Technology, Central Building of Number Two, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tabriz University Of Medical Sciences.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences.

Full name of responsible person

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Associate Professor of General Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty