Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Vasopressin versus Norepinephrine in vascular damage biomarkers in patients with septic shock

Protocol summary

Summary

This study is a Randomized Clinical Trial on 30 patients in intensive care unit (Sina hospital). Patients older than 16 years of age who has septic shock that is resistant to fluids (as defined by lack of response to 500 ml of normal saline or a requirement for vasopressor) will enter to the study and those with history of CHD, underlying chronic heart disease (NYHA class III or IV), severe hyponatremia (serum sodium less than 130 mEq/L), acute mesenteric ischemia, pregnancy or patient or legal guardian who does not consent for enrollment will exclude. Patients will randomly assign in two groups. Group one will receive infusion of 0.01-0.03u/min of vasopressin and group two 5-15 mcg/min of norepinephrine. All vasopressors infusions will titrate and tapered to maintain a target blood pressure. Patients in each group will receive the standard treatment for shock. Each patient will be monitored for 48 hours and four blood samples will be taken, first one before vasopressor administration and the other three in 12 hours, 24 hours and 48 hours. Blood samples will be used for assessment of Interleukin-1, Interleukin-6 ,Tumor Necrosis Factor-Alpha, Angiopoietin 1-2, C- Reactive Protein, and pentraxin-3

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012100311002N1**
Registration date: **2012-10-16, 1391/07/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-10-16, 1391/07/25

Registrant information

Name

Elchin Barzegar

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6695 4709

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2014-05-22, 1393/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Vasopressin versus Norepinephrine in vascular damage biomarkers in patients with septic shock

Public title

Effects of Vasopressin in Septic Shock

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients older than 16 years of age who has septic shock that is resistant to fluids (as defined by lack of response to 500 ml of normal saline or a requirement for vasopressor) within 48 hours. Exclusion criteria: Patients less than 16 years of age; history of

CHD; underlying chronic heart disease (NYHA class III or IV); severe hyponatremia (serum sodium less than 130 mEq/L); acute mesenteric ischemia; pregnancy; Patient or legal guardian does not consent for enrollment

Age

From **16 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Theran University of Medical Sciences

Street address

6th Floor, Tehran University of Medical Sciences Central Organization, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2012-09-04, 1391/06/14

Ethics committee reference number

91-02-33-18310-63707

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

Tumor Necrosis Factor-Alpha

Timepoint

before vasopressor administration and in 12 hours, 24 hours and 48 hours

Method of measurement

Elisa

2

Description

Interleukin-1

Timepoint

Before vasopressor administration and in 12 hours, 24 hours and 48 hours

Method of measurement

Elisa

3

Description

Interleukin-6

Timepoint

Before vasopressor administration and in 12 hours, 24 hours and 48 hours

Method of measurement

Elisa

4

Description

Pentraxin-3

Timepoint

Before vasopressor administration and in 12 hours, 24 hours and 48 hours

Method of measurement

Elisa

5

Description

Angiopoietin-1

Timepoint

Before vasopressor administration and in 12 hours, 24 hours and 48 hours

Method of measurement

RIA

6

Description

Angiopoietin-2

Timepoint

Before vasopressor administration and in 12 hours, 24 hours and 48 hours

Method of measurement

Elisa

7

Description
CRP
Timepoint
Before vasopressor administration and in 12 hours, 24 hours and 48 hours
Method of measurement
Elisa

8

Description
Lactate
Timepoint
Before vasopressor administration and in 12 hours, 24 hours and 48 hours
Method of measurement
Calorimetric assay

Secondary outcomes

1

Description
Mortality
Timepoint
Daily
Method of measurement
SAPSII

2

Description
Organ dysfunction
Timepoint
Daily
Method of measurement
MODS

3

Description
MAP
Timepoint
every 3 hours
Method of measurement
NIBP

Intervention groups

1

Description
Group one will receive infusion of 0.01-0.03u/min of vasopressin. vasopressin infusions will titrate and tapered to maintain a target blood pressure. This intervention will continue for 48 hours
Category
Treatment - Drugs

2

Description
Group two will receive infusion of 5-15 mcg/min of norepinephrine. Norepinephrine infusions will titrate and tapered to maintain a target blood pressure. This intervention will continue for 48 hours
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Mojtaba Mojtahedzadeh Pharm.D
Street address
31st shahriver square, Imam khomeyni street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Saedi
Street address
Enghelab Ave, Tehran University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
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Full name of responsible person

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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