

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison the effectiveness of hydroxyethyl starch (voluven) solution versus normal saline in hemorrhagic shock treatment in trauma

Protocol summary

Summary

Colloids versus crystalloids for fluid resuscitation in critically ill patients are still controversial. Mortality and morbidity is affected by rehydration. Base Excess is a well-known index of tissue hypoperfusion. The impact of crystalloid and colloid on blood Oxygen-Carrying Capacity and maintaining intravascular volume can be compared by the Base Excess measurement. Therefore, a index was measured as an indicator for the selection of the appropriate serum. This was a randomized, double-blind study designed for Comparison the effectiveness of hydroxyethyl starch (voluven) solution versus normal saline in hemorrhagic shock treatment in trauma. The study population was traumatic patients attending Imam Khomeini hospitals of Ahvaz. One hundred trauma patients with hemorrhagic shock were divided randomly into two groups: hydroxy ethyl starch (treated with 1.000 cc normal saline and 500cc hydroxyethyl starch.) and normal saline (treated with 2.000 cc normal saline) groups. Prior to determining the level of Base Excess, 10 mL blood was drawn from all patients. Base Excess again was measured after rehydration. And finally, Base Excess mean changes in the two groups were compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052114190N3**

Registration date: **2014-06-17, 1393/03/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-17, 1393/03/27

Registrant information

Name

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Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences, Vice Chancellor for Research and technology

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effectiveness of hydroxyethyl starch (voluven) solution versus normal saline in hemorrhagic shock treatment in trauma

Public title

The effect of Hydroxyethyl Starch (Voluven) On Hemorrhagic Shock Treatment.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The study included all patients with traumatic hemorrhagic shock who were referred to the Imam Khomeini hospital in Ahvaz, Iran. Exclusion criteria:

Heart failure (reduced heart function with clinical symptoms: orthopnea, exertional dyspnea, MET <4 and EF <50%); Patient who received Blood before the study completed; Patient died before completing the study; Sensitivity to serum; Transfer to the operating room before the study completed; Hepatic insufficiency (decreased liver function with decreased albumin, increased PT, clinical and liver enzymes could be increased more than 5 times); Respiratory failure (lung function decline with increasing Pco₂ > 50 or drop in Po₂ <60 or observed clinical signs of respiratory distress); Renal impairment: decreased renal function (GFR <60 mL/min/1.73 m² for at least three months, or significant proteinuria); Sepsis: The presence of SIRS (Systemic Inflammatory Response Syndrome) with prove microbial etiology; Severe anemia (Hb <10); Patients who are considered for the diagnosis of non hemorrhagic shock; Patients with a history of sensitivity to the Solutions used in this study.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, University City, Ahvaz

City

Ahvaz

Postal code

15794-61357

Approval date

2013-05-25, 1392/03/04

Ethics committee reference number

ETH-549

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

Hemorrhagic Shock

ICD-10 code

R57.9

ICD-10 code description

Failure of peripheral circulation NOS

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

Base Excess

Timepoint

Before and after fluid therapy

Method of measurement

Measured by drawing a sample of arterial blood gas (ABG)

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

Shock Index

Timepoint

after serum therapy

Method of measurement

If the shock index (heart rate / systolic blood pressure) is greater than one is considered positive.

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

First, a sample of the patient's arterial blood gas (ABG) is drawn. Afterwards the intervention group was treated with 1.000 cc normal saline and 500cc hydroxyethyl starch. After an hour, arterial blood gas was reevaluated. Voluven consumption was determined according to the protocol of the Scientific Society of Emergency Medicine. A questionnaire will be completed for each patient as well.

Category

Treatment - Drugs

2**Description**

First, a sample of the patient's arterial blood gas (ABG) is drawn. Afterwards the control group was treated with 2.000 cc normal saline. After an hour, arterial blood gas was reevaluated. A questionnaire will be completed for

each patient as well.

Category

Treatment - Drugs

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

Imam Khomeini Hospital

Full name of responsible person

Dr. Ali Askari Darian

Street address**City**

Ahvaz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research and Technology
Development-Ahvaz Jondishapur University of
Medical Sci

Full name of responsible person

Dr. Nader Saki

Street address

Ground Floor, Faculty of Rehabilitation Sciences
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Grant name

ندارد

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research and Technology
Development-Ahvaz Jondishapur University of Medical
Sci

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**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

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Position

Emergency Medicine resident

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Position

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Full name of responsible person

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Medical Student

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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