Clinical Trial Protocol
Iranian Registry of Clinical Trials
29 Jul 2019

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
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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
None

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**
Ahvaz

**City**

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**Sponsors / Funding sources**

1

**Sponsor**

Name of organization / entity
Vice Chancellor for Research and Technology Development-Ahwaz Jundishapur University of Medical Sci

Full name of responsible person
Dr. Nader Saki

Street address
Ground Floor, Faculty of Rehabilitation Sciences, Ahvaz Jundishapur University of Medical Sciences, Ahvaz

City
Ahvaz

Grant name
نادر

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-Ahwaz Jundishapur 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
empty

Type of organization providing the funding
empty

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**Person responsible for general inquiries**

**Contact**

Name of organization / entity
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Full name of responsible person
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Position
Emergency Medicine resident

Other areas of specialty/work

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**Sharing plan**

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol