Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effect of 5% Albumin Infusion with Ringer Lactate Serum on Replacement of Patients' Bleeding during Surgery on the Function of Renal and Coagulation System and Their Electrolytes after Surgery

Protocol summary

Study aim
Effect of 5% albumin on replacement of hemorrhage during surgery on renal and coagulation system and patient's serum electrolytes after surgery

Design
Simple randomization using random number table and Phase 3 clinical trial. Groups are parallel. Patients, analyzers and outcome assessor will not be aware of group type.

Settings and conduct
This clinical trial will be conducted at General hospital of Ayatollah Kashani in Shahrekord. Patients will be randomly divided into intervention (Albumin solution 5%) and control (Ringer lactate serum) groups for assessing preoperative renal function and coagulation status at 6, 12 and 24 hours after surgery.Patients, analyzers and outcome assessor will not be aware of group type.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 18 and 75 years, anesthesia class 1 and 2, blood urea less than 38.5 mg / dl, blood creatinine less than 1.3 mg / dl Exclusion criteria: history of liver, kidney, heart disease, coagulation and anticoagulant use

Intervention groups
Intervention group: Albumin 5% will be used to compensate for bleeding. The control group will receive 3 times the amount of bleeding ringer lactate to compensate for bleeding.

Main outcome variables
Changes in Coagulation Tests (PT, PTT, INR), Renal Tests (BUN, Cr, Na, Ca, K)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191009045037N1**
Registration date: **2019-11-30, 1398/09/09**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-30, 1398/09/09**
Update count: **0**

Registration date
2019-11-30, 1398/09/09

Registrant information

Name
Hossein Madineh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-10-23, 1396/08/01

Expected recruitment end date
2020-07-22, 1399/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the Effect of 5% Albumin Infusion with Ringer Lactate Serum on Replacement of Patients' Bleeding during Surgery on the Function of Renal and Coagulation System and Their Electrolytes after Surgery

Public title
The effect of injectable albumin on renal and coagulation system activity
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Men and women 18 to 75 years The risk of anesthesia is 1 or 2 with the division of the American Anesthesia Association A blood urea of less than 38.5 mg / dl Have a blood creatinine of less than 1.3 mg / dL Blood platelets range between 150,000 and 300,000 Patient INR less than 1.2 The patient's consent form must be signed by the patient
Exclusion criteria:
Patient with a history of liver disease Patient with a history of heart failure Patient history of kidney disease Patient with a history of coagulopathy
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will conduct based on permuted block randomization method. Each block will have capacity for 4 subjects. Then, within each block, subjects will be randomly assigned to Albumin 5% or Ringer lactate. Random assignment will be done using a random number table
Blinding (investigator's opinion)
Double blinded
Blinding description
The participant was under general anesthesia during the intervention and the outcome assessor and analyzer received the results of the study as group A and B and were not aware of Albumin group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahrekord University of Medical Sciences
Street address
Ayatollah Kashani Ave Shahrekord University of Medical Sciences 8815713471
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Approval date
2017-01-21, 1395/11/02
Ethics committee reference number
IR.SKUMS.REC.1395.211

Health conditions studied

1

Description of health condition studied
Chronic kidney disease
ICD-10 code
N18
ICD-10 code description
Chronic kidney disease (CKD)

2

Description of health condition studied
Coagulapathy
ICD-10 code
D68.9
ICD-10 code description
Coagulation defect, unspecified

Primary outcomes

1

Description
The effect of albumin on renal system activity
Timepoint
Preoperatively and 6, 12 and 24 hours postoperatively
Method of measurement
Calometric

Secondary outcomes

1

Description
The effect of albumin on coagulation activity
Timepoint
Preoperatively and 6,12,24 hours postoperatively

Method of measurement
Coagulometer

Intervention groups

1

Description
Intervention group: Intraoperative fluid therapy in the this group would be albumin 5% equal to bleeding volume. To study patients' coagulation status, Prothrombin time (PT), Partial thromboplastin time (PPT), and INR tests. Measurements will be at preoperative times, at 6, 12, and 24 hours after surgery. In addition , concentrations of electrolytes (sodium, potassium and calcium), urinary output, BUN and creatinine will also be collected.
Category
Treatment - Drugs

2

Description
Control group: Intraoperative fluid therapy in the this group would be Ringer lactate with three times of bleeding volume. To study patients' coagulation status, Prothrombin time (PT), Partial thromboplastin time (PPT), and INR tests. Measurements will be at preoperative times, at 6, 12, and 24 hours after surgery. In addition , concentrations of electrolytes (sodium, potassium and calcium), urinary output, BUN and creatinine will also be collected.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatolah Kashani hospital
Full name of responsible person
Hossein Madineh
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Parrastar St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Kamal Solati
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Ayatollahe Kashani St
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Phone
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Email
info@skums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Hossein Madineh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Medical Education
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Clinical characteristics and laboratory information of patients, sample collection method, inclusion and exclusion criteria, intraoperative bleeding, intraoperative fluid therapy, pre- and postoperative tests, information analysis method and information results

When the data will become available and for how long
2020

To whom data/document is available
Ministry of Health and Medical Education of the Islamic Republic of Iran

Under which criteria data/document could be used
For information on appropriate treatment and permission from the research officer

From where data/document is obtainable
From researcher hosseinmadineh@gmail.com and Shahrekord University of Medical Sciences: info@skums.ac.ir :

What processes are involved for a request to access data/document
Documentary Requirements for Information Required and Letter from his Affiliated Institution After Investigating If a Researcher and Shahrekord University of Medical Sciences Agree Within a Month

Comments