

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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)

Phone

+98 38 3226 4835

Email address

hosseinmadineh@gmail.com

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**

Coagulopathy

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

Street address

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

Street address

Ayatollahe Kashani St

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8815713471

Phone

+98 38 3333 0061

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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Person responsible for scientific 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

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Person responsible for updating data

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Position

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Other areas of specialty/work

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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