

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison of serum viscosity between patients whom infused human serum albumin5% with the patients whom infused normal saline

#### Protocol summary

##### Summary

In this study with the goal of comparison of serum viscosity between patients whom infused human serum albumin5% with the patients whom infused normal saline, patients with ASA class I and II in the range of 20 to 50 years old candidate for low to moderate risk minor surgery .Without a history of hypertension, diabetes mellitus, ischemic heart disease, coagulopathy, receiving anti coagulant and antiplatelet factors and BMI higher than 30 and surgery duration longer than 2 hours and large fluid shift during surgery were selected randomly in two group of 28 cases .10ml.of venous blood obtained in the heparinised syringe(containing 1000 unit heparin) from all patient before fluid infusion and also one hour after the end of fluid infusion ( on liter of normal saline or albumin 5%) and the blood samples kept immobile for several hours and then after the separation of the serum phase from the blood cells. the serum transferred to a 20 ml. syringe and this syringe connected to an infusion pump with a rate of 1 ml per minute while a 3- way stop-cock placed at the exit of the syringe. The serum had two ways to pass through them: 1) a 23 gauge needle. 2) Through an extension tube which was filled with distilled water. The height of the column of the water in the extension tube in millimeter was recorded and the viscosity value calculated with loading this formula:  $\eta = (\pi p r^4)/(8' Q l)$

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013022312573N1**  
Registration date: **2013-08-18, 1392/05/27**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-08-18, 1392/05/27

##### Registrant information

###### Name

Mozhde Jalali

###### Name of organization / entity

Tehran University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6634 8504

###### Email address

jalali\_m@razi.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice-chancellor for research -Tehran University of Medical Science

##### Expected recruitment start date

2012-12-20, 1391/09/30

##### Expected recruitment end date

2013-03-20, 1391/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of serum viscosity between patients whom infused human serum albumin5% with the patients whom infused normal saline

##### Public title

effect of saline and albumin %5 on serum viscosity

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

Inclusion criteria: All patients with ASA class I and II in the range of 20 to 50 years old candidated for low to momerate risk minor surgery. Exclusion criteria: patients with a history of hypertension; diabetes mellitus; ischemic heart disease; coagulopathy; receiving anti coagulant and antiplatlate factor; patients with BMI highier than 30; surgery duration longer than 2 hours and large fluid shift( more than 60ml/kg crystalloid infusion needed) during surgery

#### **Age**

From **20 years** old to **50 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **56**

#### **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**

Tehran University of Medical Science

##### **Street address**

Central Department of Tehran University, 6th Floor,  
Qods Ave, keshavarz boulevard, Tel.: 02188987381-2

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2013-01-23, 1391/11/04

#### **Ethics committee reference number**

2738/130/91/3

### **Health conditions studied**

#### **1**

#### **Description of health condition studied**

plasma viscosity

#### **ICD-10 code**

R70.1

#### **ICD-10 code description**

Abnormal plasma viscosity

### **Primary outcomes**

#### **1**

#### **Description**

blood serum viscosity

#### **Timepoint**

before infusion of any fluid ,one hour after infusion of normal saline or albumin 5%

#### **Method of measurement**

5cc of patient's serum was transfused with a rate of 1 ml per minute while a 3- way stop-cock placed at the exit of the syringe. The serum had two ways to pass through them: 1) a 23 gauge needle. 2) Through an extension tube which was filled with distilled water. The height of the column of the water in the extension tube in millimeter was recorded and the viscosity value calculated with loading this formula:  $\eta = (\pi p r^4)/(8' Q l)$

### **Secondary outcomes**

#### **1**

#### **Description**

1)determine the serum viscosity by age.2) determine the serum viscosity by the type of anesthesia 3)determine the serum viscosity by the type of surgery

#### **Timepoint**

befor infusion of any fluid

#### **Method of measurement**

5cc of patient's serum was transfused with a rate of 1 ml per minute while a 3- way stop-cock placed at the exit of the syringe. The serum had two ways to pass through them: 1) a 23 gauge needle. 2) Through an extension tube which was filled with distilled water. The height of the column of the water in the extension tube in millimeter was recorded and the viscosity value calculated with loading this formula:  $\eta = (\pi p r^4)/(8' Q l)$

### **Intervention groups**

#### **1**

#### **Description**

IV infusion of normal saline over one hour in control group

#### **Category**

Diagnosis

#### **2**

#### **Description**

IV infusion of serum albumin 5% over one hour in intervention group

#### **Category**

Diagnosis

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Operation room of Sina hospital

**Full name of responsible person**

**Street address**

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

School of Public Health, Tehran University of Medical

**Full name of responsible person**

Dr. Akbar Fotuhi

**Street address**

Department of Epidemiology and Biostatistics, School of Public Health, Tehran University of Medical Sciences, PO Box: 14155-6446

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

School of Public Health, Tehran University of Medical

**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**

Tehran University of Medical Science

**Full name of responsible person**

Dr. Mozhde Jalali

**Position**

Resident of Anesthesiology

**Other areas of specialty/work**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

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Assistant

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## Person responsible for updating data

### Contact

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Associated Professor

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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*