

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of intermittent normal saline bolus during hemodialysis on adequacy of dialysis

#### Protocol summary

##### Summary

1) Objectives: The goal of the study is to investigate effect of intermittent normal saline bolus during hemodialysis on adequacy of dialysis. 2) Design: Our study design is a 4th phase of a randomized, cross over clinical trial. Fifty hemodialysis patients are chosen from Pan Azar Medical Educational Center, Gorgan, based on inclusion and exclusion criteria. They are allocated randomly into intervention and control group. 3) Setting and conduct: At the beginning of the study, we will measure the adequacy of dialysis at the first hemodialysis session. Then, the intervention is implemented on intervention group. After next two hemodialysis sessions, adequacy of dialysis is again measured. Blood clot in the venous chamber and dialyzer will be assessed and graded visually at the end of each hemodialysis session based on a grading table. Then one week is allowed for wash out period after which the groups are crossed over and all the steps will be repeated. 4) Participants: Participants are hemodialysis patients, at least 18 years old, and on maintenance hemodialysis for more than six months (4 hours, and three times per week), from Pan Azar Medical Educational Center, Gorgan. Their access types are Arteriovenous Fistula or Graft. 5) Intervention: Intervention is infusing 100 milliliters of normal saline, 3 times during hemodialysis in addition to following the standard protocol. The control group is dialyzed based on standard protocol. 6) Main outcome measures: The adequacy of dialysis is the primary outcome and the quality of clot formation in the venous chamber and dialyzer is the secondary outcome of the study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015100324303N1**

Registration date: **2015-11-14, 1394/08/23**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-11-14, 1394/08/23

##### Registrant information

###### Name

Mitra Shirashiani

###### Name of organization / entity

Golestan University Of Medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

mitra.shirashiani@goums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research and Innovation of Golestan University of Medical Sciences

##### Expected recruitment start date

2015-11-06, 1394/08/15

##### Expected recruitment end date

2015-12-21, 1394/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of intermittent normal saline bolus during hemodialysis on adequacy of dialysis

##### Public title

Effect of intermittent normal saline bolus during hemodialysis on adequacy of dialysis

ir.goums.rec.1394.140

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion Criteria: Patients with end-stage renal disease treated with maintenance hemodialysis for at least six months; Age above 18 years old; Willingness to participate in the study; On 3 times per week, 4-hours long maintenance hemodialysis; Arteriovenous Fistula or Graft access type; Receives 5000 units of unfractionated heparin during each session of hemodialysis; Hemoglobin concentration 9 to 14 grams per deciliter. Exclusion Criteria: Having acute debilitating disease (cardiovascular, hypertension, cancer and acute infection); Having systolic blood pressure below 90 and above 160 mm Hg.

## Age

From **18 years** old

## Gender

Both

## Phase

4

## Groups that have been masked

*No information*

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Crossover

## Other design features

50 patients will be allocated randomly (Block Randomization) in two groups (intervention and control).

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

##### Street address

Falsafi Educational Campus, Hirkan Boulevard

##### City

Gorgan

##### Postal code

4934174515

#### Approval date

2015-10-04, 1394/07/12

#### Ethics committee reference number

## Health conditions studied

### 1

#### Description of health condition studied

Hemodialysis

#### ICD-10 code

Z49

#### ICD-10 code description

Z49.1

## Primary outcomes

### 1

#### Description

Adequacy of Hemodialysis (KT/V) and Urea Reduction Ratio (URR)

#### Timepoint

At first and third session of hemodialysis. After a one-week washout time, again at the first and third session of hemodialysis.

#### Method of measurement

Pre and post dialysis serum urea and calculation of URR and KT/V using formula recommended by Ministry of Health and Medical Education

## Secondary outcomes

### 1

#### Description

Clot formation in extracorporeal tubing

#### Timepoint

At the end of each hemodialysis sessions

#### Method of measurement

By direct observation and grading

## Intervention groups

### 1

#### Description

Intervention Group: One Hundred milliliters of normal saline is flushed through the arterial line of extracorporeal tubing three times during the 4-hour period of hemodialysis (once every hour) in addition to following the hemodialysis standard protocol; i.e., receiving 5000 units of unfractionated heparin during hemodialysis. The intervention is for 2 consecutive hemodialysis sessions.

#### Category

Treatment - Other

### 2

#### Description

Control Group: The group is dialyzed based on the standard protocol: Five thousands units of unfractionated

heparin are given during the 4-hour period of hemodialysis but no intermittent saline flush.

**Category**

Treatment - Other

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

Panj Azar Medical Educational Center

**Full name of responsible person**

Mitra Shirashiani

**Street address**

Panj Azar Street

**City**

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

Vice Chancellor for Research and Innovation,  
Golestan University of Medical Sciences

**Full name of responsible person**

Masoud Khoshnia, MD

**Street address**

Falsafi Educational Campus, Hirkan Boulevard

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Gorgan

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

Yes

**Title of funding source**

Vice Chancellor for Research and Innovation, Golestan  
University of Medical Sciences

**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**

Golestan University of Medical Sciences

**Full name of responsible person**

Einollah Mollaei

**Position**

Master of Nursing, Clinical instructor

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**Web page address****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*