

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of priming with heparin and normal saline on adequacy of hemodialysis in hemodialysis patients

#### Protocol summary

##### Study aim

Determination the effect of priming with heparin - normal saline on adequacy of hemodialysis in hemodialysis Patients

##### Design

A randomized clinical trial with a control group, with two parallel groups

##### Settings and conduct

The present study is a randomized clinical trial on two groups of 72 patients undergoing hemodialysis in Hamedan. In the intervention group, hemodialysis device priming will be done for patients with normal saline plus heparin for one month. In the control group, priming will be performed using normal saline. The adequacy of hemodialysis patients will be examined using the adequacy calculation formula for hemodialysis.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Perform hemodialysis three times a week, End stage renal failure, Age 18 to 85 years old  
exclusion criteria: Unwillingness to continue to participate in the study, Failure to perform hemodialysis regularly.

##### Intervention groups

In the intervention group, hemodialysis device priming will be done for patients with normal saline plus heparin(1000units) for one month.

##### Main outcome variables

Hemodialysis adequacy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160110025929N25**

Registration date: **2019-07-28, 1398/05/06**

Registration timing: **prospective**

Last update: **2019-07-28, 1398/05/06**

Update count: **0**

##### Registration date

2019-07-28, 1398/05/06

##### Registrant information

###### Name

Mehdi Molavi Vardanjani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3422 5056

###### Email address

m.molavi@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-21, 1398/05/30

##### Expected recruitment end date

2020-08-20, 1399/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of priming with heparin and normal saline on adequacy of hemodialysis in hemodialysis patients

##### Public title

Effect of priming with heparin - normal saline on adequacy of hemodialysis

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Age 18 to 85 years old End stage renal failure Perform hemodialysis three times a week

**Exclusion criteria:**

Unwillingness to continue to participate in the study  
Failure to perform hemodialysis regularly

**Age**

From **18 years** old to **85 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **72**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple random allocation will be done using a random number table. Patients will be randomly divided into two groups intervention(A) and control (B).

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Hamadan University of Medical Sciences

**Street address**

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

**City**

Hamadan

**Province**

Hamadan

**Postal code**

38698-65178

**Approval date**

2019-07-21, 1398/04/30

**Ethics committee reference number**

IR.UMSHA.REC.1398.329

**Health conditions studied**

1

**Description of health condition studied**

Chronic kidney disease

**ICD-10 code**

N18.5

**ICD-10 code description**

Chronic kidney disease, stage 5

**Primary outcomes**

1

**Description**

Hemodialysis adquacy

**Timepoint**

Before and immediately after each hemodialysis

**Method of measurement**

Blood urea and creatinine measurements by blood test

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: In the intervention group, the hemodialysis device priming will be done using normal saline plus 1000 units of heparin for one month.

**Category**

N/A

2

**Description**

Control group: In the control group, the priming of the hemodialysis device will be performed using normal saline.

**Category**

Other

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Besat hospital

**Full name of responsible person**

Reza Borzou

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Borzou@umsha.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Saeed Bashirian

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s\_bashirian@umsha.ac.ir

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

No

**Title of funding source**

Deputy of research and technology

**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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Reza Borzou

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Tayebeh Nazaridoust

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## **Sharing plan**

### **Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

### **Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

### **Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

## **Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

### **Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

### **Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

### **Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available