

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of lowering dialysate temperature on the quality of hemodialysis in patients undergoing hemodialysis in 5t Azar hospital

#### Protocol summary

##### Summary

This is a clinical trial study with randomized controlled design. The purpose of this study is to determine the effect of reducing dialysate temperature on the quality of hemodialysis in dialysis patients. Our samples are included the patients undergoing hemodialysis in 5th Azar hospital who have the inclusion criteria during one month before of study. Simple random sampling technique was employed to select 50 patients that divided into 2 groups of 25 persons. In crossover study, patients are assessed during 24 dialysis sessions; the first group received hemodialysis for 12 sessions using cool dialysate (35.5°C) and the second group is on hemodialysis with standard dialysate temperature (37°C). Then the method of treatment is replaced in two groups for the next 12 sessions. Hemodynamic parameters including SBP, DBP and heart rate (HR) are recorded hourly, before, during and after dialysis. Clinical complaints and treatment interventions related to hypotension are noted. Oral temperature is measured before and immediately after dialysis. For all patients, dialysis adequacy is measured 5 times and Petersburg Sleep Quality Index (PSQI) questionnaire is checked for three stages; before the intervention, before moving groups and at the end of the study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201306268140N2**  
Registration date: **2013-07-14, 1392/04/23**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-07-14, 1392/04/23

#### Registrant information

##### Name

Einollah Mollaei

##### Name of organization / entity

Golestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 1442 6900

##### Email address

mollaei@goums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Deputy of Research and Technology Golestan University of Medical Sciences

#### Expected recruitment start date

2013-06-22, 1392/04/01

#### Expected recruitment end date

2013-08-23, 1392/06/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of lowering dialysate temperature on the quality of hemodialysis in patients undergoing hemodialysis in 5t Azar hospital

#### Public title

Effect of lowering dialysate temperature on the quality of hemodialysis

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: the samples are included the patients undergoing hemodialysis at 5th Azar hospital having:

hypotension in more than 30 percent of dialysis sessions (more than three sessions), during one month before the study; three times dialysis per week with sodium bicarbonate solution; patients did not receive analgesic, anti-hypertensive and anti-spasm during four hours before of dialysis; no history of chronic infections, heart failure, chronic lung disease, drugs / alcohol abuse or require of treatment for mental disorders, severe anemia, coronary artery disease; age more than 18 years old and more than three month's dialysis treatment.

#### Age

From **18 years** old to **75 years** old

#### Gender

Both

#### Phase

N/A

#### 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

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Golestan University of Medical Sciences

##### Street address

Kilometer 2 Gorgan sari -Golestan University of Medical Sciences

##### City

Gorgan

##### Postal code

#### Approval date

2013-03-17, 1391/12/27

#### Ethics committee reference number

340791122702

## Health conditions studied

### 1

#### Description of health condition studied

End stage kidney disease

#### ICD-10 code

N18.5

#### ICD-10 code description

End stage kidney disease

## Primary outcomes

### 1

#### Description

dialysis adequacy

#### Timepoint

5 times

#### Method of measurement

Laboratory method with URR

### 2

#### Description

Sleep Quality

#### Timepoint

3 times

#### Method of measurement

Petersburg Sleep Quality Index (PSQI) questionnaire

### 3

#### Description

Blood pressure

#### Timepoint

hourly, before, during and after dialysis

#### Method of measurement

Blood pressure based on mm Hg, monitoring by Gambro AK96 dialysis machine

### 4

#### Description

Temperature

#### Timepoint

before and immediately after dialysis

#### Method of measurement

Thermometer

### 5

#### Description

Muscle cramps

#### Timepoint

pre, intra & post dialysis

#### Method of measurement

checklist

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In crossover study, patients are assessed during 24 dialysis sessions; the first group received hemodialysis

for 12 sessions using cool dialysate (35.5°C) and the second group is on hemodialysis with standard dialysate temperature (37°C). Then the method of treatment is replaced in two groups for the next 12 sessions. Each patient gets dialysis once with routine temperature and once with cool dialysate. Patients are assessed during 24 dialysis sessions; the first group receives hemodialysis for 12 sessions using cool dialysate (35.5°C) and the second group is on hemodialysis with standard dialysate temperature (37°C). Then the method of treatment is replaced in two groups for the next 12 sessions. During the study, all the dialysis conditions are maintained the same except temperature of dialysate (37°C or 35.5°). All patients are on hemodialysis using GAMRO AK96 hemodialysis machine.

**Category**

Prevention

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

Dialysis therapy 5t Azar hospital

**Full name of responsible person****Street address****City**

Gorgan

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

Golestan University of Medical Sciences

**Full name of responsible person**

Golalipour Mohammad Jafar

**Street address**

Kilometer 2 Gorgan Sari , Golestan University of Medical Sciences ,Gorgan

**City**

Gorgan

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

Yes

**Title of funding source**

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**

Mollaie Einollah

**Position**

Assistant Professor, Department of Medical Surgical Nursing

**Other areas of specialty/work****Street address**

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**Email**

**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*