

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The effects of cool dialysate on adequacy and Common complications during hemodialysis in dialysis patients

#### Protocol summary

##### Summary

This study is a Triple-blind clinical trial Which aims to determine the effect of cool dialysis on adequacy and Common complications in the Arak center dialysis. The study population consisted of 80 patients with end-stage renal failure in the age range 18 to 80 years, that they are at least three months before to become permanent dialysis And stratified random sampling method based on random numbers table will be in both groups. Intervention will be in two stages. In the first stage one group with a solution of 35 C° dialysis and the other group with the 36/5 with the solution. In the next step by moving the treatment group than uses from the method of the other groups. every stage consists of 4 sub sessions. blood pressure and body temperature control before and after dialysis and in the first hour and the second and third during dialysis. in the 4 and 8 sessions blood sample control before and after dialysis to assess the adequacy of dialysis.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017032633145N1**

Registration date: **2017-06-24, 1396/04/03**

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

Last update:

Update count: **0**

##### Registration date

2017-06-24, 1396/04/03

##### Registrant information

##### Name

Fatemeh Ahmadi

##### Name of organization / entity

Lorestan University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 3312 0140

##### Email address

fa.ahmadi21@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Deputy of Lorestan University of Medical Sciences

##### Expected recruitment start date

2017-05-22, 1396/03/01

##### Expected recruitment end date

2017-08-22, 1396/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of cool dialysate on adequacy and Common complications during hemodialysis in dialysis patients

##### Public title

The effect of reduction of dialysate temperature in hemodialysis patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients that are in end stage renal disease and Minimum of three months before participating in the study are hemodialysis; Age over 18 years, None of the blood pressure-lowering drugs on the morning of dialysis are not used; Absence of cardiac disorders such as MI or having a pacemaker; No risk of severe anemia  $Hb < 8$  ; No one have cancer; Lack of thyroid disorders (due to temperature changes that may

occur). exclusion criteria: Unwillingness to continue treatment, The loss of one of the inclusion criteria, the problem of vascular access, Severe heart disorders such as unstable angina and MI occur during the study; Severe shivering, so that the patient may not be able to continue dialysis; Severe and uncontrollable vomiting.

#### **Age**

From **18 years** old to **80 years** old

#### **Gender**

Both

#### **Phase**

N/A

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

*No information*

#### **Sample size**

Target sample size: **80**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Triple blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Crossover

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Research Committee, Lorestan university of medical sciences.

##### **Street address**

Department of Nursing, School of Nursing and Midwifery, Lorestan University of Medical Sciences.

##### **City**

Khorramabad

##### **Postal code**

381351698

#### **Approval date**

2017-05-30, 1396/03/09

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

LUMS.REC.1396.262

## **Health conditions studied**

### 1

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

hemodialysis

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

Z49.0

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

Preparatory care for dialysis

## **Primary outcomes**

### 1

#### **Description**

Hemodialysis adequacy

#### **Timepoint**

End of 4 Session and of 8 Session

#### **Method of measurement**

Measurement of Urea before and after dialysis, according to a formula Daygr DOS 2

### 2

#### **Description**

Common complications during dialysis

#### **Timepoint**

During dialysis

#### **Method of measurement**

check list

## **Secondary outcomes**

### 1

#### **Description**

blood pressure

#### **Timepoint**

Before and after dialysis and in the first, second and third hour dialysis

#### **Method of measurement**

Digital manometer cuff

### 2

#### **Description**

Temperatures

#### **Timepoint**

Before and after dialysis and in the first, second and third hour dialysis

#### **Method of measurement**

Digital thermometer

### 3

#### **Description**

Feeling cold and chills

#### **Timepoint**

During dialysis

#### **Method of measurement**

During dialysis

## **Intervention groups**

### 1

#### **Description**

Firstly: dialysis for the first group 36.5 and for the second group is set to 35 ° C

#### **Category**

Other

**2**

**Description**

Secondly: dialysis for the second group 36.5 and for the first group is set to 35 ° C

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Arak dialysis center

**Full name of responsible person**

Fatemeh Ahmadi, MSc of Nursing Education in Medical Surgical Field

**Street address**

Lorestan university of medical sciences

**City**

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Lorestan University of Medical Sciences

**Full name of responsible person**

Dr. Morovat Taheri-Kalani

**Street address**

Vice Chancellor for Research, Lorestan University of Medical Sciences

**City**

Khorramabad

**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, Lorestan 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**

Lorestan University of Medical Sciences

**Full name of responsible person**

Fatemeh Ahmadi

**Position**

MSc of Nursing Education in Medial Surgical Field

**Other areas of specialty/work**

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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*