

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

Khoramabad

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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Person responsible for scientific inquiries

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Ph.D

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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