

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of cold dialysate on post-dialysis fatigue syndrome

Protocol summary

Summary

This study is a double blind clinical trial To investigate the effect of cool dialysis on post-dialysis fatigue syndrome in Arak Vali -asr . The number 46 of patients with end-stage renal disease will be selected according to the criteria with purposive sampling And will be simple random sampling in both groups A and B . Each patient will hemodialysis in group A, three times a week (every other day) with a dialysate temperature of 37 ° C and then in the second week three sessions (every other day) with temperature 35/5° C. group B is In contrast to group A. At the end of each dialysis session will be completed once Piper Fatigue Scale for each patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014082518928N1**
Registration date: **2015-02-12, 1393/11/23**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-12, 1393/11/23

Registrant information

Name

Zohreh Gholami

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Arak University of Medical Sciences

Expected recruitment start date

2014-09-13, 1393/06/22

Expected recruitment end date

2014-12-21, 1393/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cold dialysate on post-dialysis fatigue syndrome

Public title

The effect dialysate temperature reduce on dialysis patients fatigue

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age over 18 years, diagnosis end stage renal disease, Having a degrees from fatigue, , regular visit three times a week for dialysis ,Hemodialysis treatment for at least 6 months, stable hemodynamic conditions ,Willingness to participate in the study. Hearing ability, speech and consciousness acceptable to answer the questions, Absence of cardiovascular disorders such as myocardial infarction, non-anemia H b<8 exclusion criteria: Unwillingness to continue treatment, complications during dialysis requires immediate medical attention, The loss of one of the inclusion criteria, the problem of vascular access, The incidence of severe cardiac problems during dialysis, Chills so severe that the patient is not 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: **46**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Arak, Basij Square, pardis University of Medical Sciences, Faculty of Nursing and Midwifery

City

Arak

Postal code

3819693345

Approval date

2014-06-11, 1393/03/21

Ethics committee reference number

93-163-18

Health conditions studied

1

Description of health condition studied

End stage renal disease

ICD-10 code

XIV

ICD-10 code description

N17-N19 Renal failure

Primary outcomes

1

Description

post diaysis Fatigue

Timepoint

After each three dialysis session

Method of measurement

piper fatigue scale

Secondary outcomes

1

Description

temperature

Timepoint

Before and after each dialysis session

Method of measurement

Mercury thermometer axillary

2

Description

Feeling cold and chills

Timepoint

During dialysis

Method of measurement

Monitoring patient

Intervention groups

1

Description

dialysate temperature will be reduced to 35/5° C for group A in the second week and for group B in the first week and all patients(CROSSOVER) will be undergoing hemodialysis for three sessions with each temperature (35/5 and 37 ° C)

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Vali-asr

Full name of responsible person

Dr Mahbubeh. Sajjadi

Street address

Iran, Arak, Sardasht, Faculty of Nursing and Midwifery

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Arak University of Medical Sciences

Full name of responsible person

Mr.Babaie

Street address

Arak, Basij Square, pardis University of Medical Sciences

City

Arak

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Deputy of Arak 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

Arak University of Medical Sciences

Full name of responsible person

zohreh gholami

Position

Nurse

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