

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of cyproheptadine on appetite ,laboratory and enteropometric indices in chronic renal failure pateint on hemodialysis

Protocol summary

Study aim

Determining the effect of cyproheptadine drug on appetite, laboratory and anthropometric indicators of chronic kidney patients undergoing hemodialysis

Design

Clinical trial with control group with parallel groups, double-blind, randomized, phase 3 on 124 patients. Available sampling was used for randomization.

Settings and conduct

124 patients from 18 to 80 years of age referring to the hemodialysis department of Shahid Jalil Yasouj Hospital are eligible for selection and after obtaining informed consent, they are randomly assigned to two intervention and control groups. For the intervention group, in addition to routine treatment, cyproheptadine tablets will be administered at a dose of 4 mg daily and the placebo for control group. After three months, laboratory and anthropometric parameters and appetite of the patients will be measured.

Participants/Inclusion and exclusion criteria

log : Chronic kidney patients undergoing hemodialysis, 18 to 80 years old Patients who undergo dialysis twice a week with good efficacy. Willingness of people to participate in the plan Absence of accompanying disease that causes the patient's anorexia. Not taking drugs that increase appetite. Exit: Migration or death of the patient Dissatisfaction with the continuation of treatment In case of other infectious or chronic diseases during the research period Patients who have undergone organ transplant surgery.

Intervention groups

In addition to routine treatment, intervention group patients will be prescribed cyproheptadine 4 mg daily, and placebo for control group will be prescribed. After three months, the laboratory and anthropometric indicators and appetite of the patients will be measured again

Main outcome variables

Improving the physiological conditions and increasing the

quality of life of patients undergoing hemodialysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220329054368N2**

Registration date: **2023-04-17, 1402/01/28**

Registration timing: **prospective**

Last update: **2023-04-17, 1402/01/28**

Update count: **0**

Registration date

2023-04-17, 1402/01/28

Registrant information

Name

Farnaz sadat Javanmardi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3229 8671

Email address

farnaz.javanmardi@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-21, 1402/02/31

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Investigating the effect of cyproheptadine on appetite ,laboratory and enteropometric indices in chronic renal failure pateint on hemodialysis
Public title	Investigating the effect of cyproheptadine in chronic kidney patients
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Chronic kidney patients undergoing dialysis between 18 and 80 years of age, at least three months have passed since the start of dialysis. Patients who undergo dialysis twice a week with good efficacy. People's willingness to participate in the project. Absence of accompanying disease (infection, uncompensated heart failure, malignancy, liver cirrhosis, covid-19) that causes the patient's anorexia. Not taking drugs such as tricyclic antidepressants and corticosteroids that increase appetite.
Exclusion criteria:	Patient migration or death Dissatisfaction with the continuation of treatment by the patient. If other infectious or chronic diseases occur during the research period. Patients who underwent organ transplant surgery.
Age	From 18 years old to 80 years old
Gender	Both
Phase	3
Groups that have been masked	- Participant - Investigator
Sample size	Target sample size: 124
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization will be done in a random block method. The size of the blocks is chosen randomly (for example, blocks of 4, 8, and 12) where there is an equal number of each group in each block.
Blinding (investigator's opinion)	Double blinded
Blinding description	The researcher and the participant do not know which drug is the main drug and which is the placebo.
Placebo	Used
Assignment	Parallel
Other design features	So far, the effect of cyproheptadine on appetite and laboratory parameters of chronic kidney patients has not been investigated.

Secondary Ids	empty
Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics committee of Yasouj University of Medical Sciences
Street address	Yasouj University of Medical Sciences , Shahid Motahari Blvd.,
City	Yasouj
Province	Kohgiluyeh-va-Boyer-Ahmad
Postal code	07433337230
Approval date	2022-11-14, 1401/08/23
Ethics committee reference number	IR.YUMS.REC.1401.127
Health conditions studied	
1	
Description of health condition studied	Chronic kidney patients undergoing hemodialysis
ICD-10 code	N18.5
ICD-10 code description	Chronic kidney disease, stage 5
Primary outcomes	
1	
Description	appetite
Timepoint	Before and three months after the intervention
Method of measurement	NMA questionnaire
2	
Description	Anthropometric indicators
Timepoint	Before and three months after the intervention
Method of measurement	Meter
3	
Description	Laboratory indicators
Timepoint	

Before and three months after the intervention

Method of measurement

cycmax

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Administration of cyproheptadine
4mg daily

Category

Treatment - Drugs

2

Description

Control group: Placebo administration

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Jalil Hospital

Full name of responsible person

Ahmad Mokhtari

Street address

Shahid Jalil Hospital , Qarani Blvd

City

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Kohgiluyeh-va-Boyerahmad

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07433337004

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jalilhospital@yums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasouj University of Medical Sciences

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

Yasouj University of Medical Sciences

Full name of responsible person

Farnaz sadat Javanmardi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Investigating the effect of cyproheptadine on appetite
,laboratory and enteropometric indices in chronic renal
failure pateint on hemodialysis

When the data will become available and for how long

After acceptance of the article

To whom data/document is available

researchers

Under which criteria data/document could be used

In order to expand research

From where data/document is obtainable

Email to the responsible person

What processes are involved for a request to access data/document

Reviewing research documents of the applicant

Comments