

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Study of the effect of hemodialysis on retinal and choroidal thickness in patients with chronic renal disease who underwent hemodialysis in the dialysis ward of Imam Khomeini Hospital

Protocol summary

Study aim

Study of the effect of hemodialysis on retinal and choroidal thickness in patients with chronic renal disease who underwent hemodialysis in the dialysis ward of Imam Khomeini Hospital

Design

This study is a nonblinded clinical trial. The study population will be included all patients with chronic kidney failure that referred to Imam Khomeini Hospital of Kermanshah. 83 eligible patients will be selected conveniently and will undergo dialysis

Settings and conduct

The study, which will be conducted at Imam Khomeini Hospital of Kermanshah, is not blinded one. In all patients, complete ophthalmologic examinations including IOP, VA and fundus examination, refraction and macular and choroidal OCT are performed 30 minutes prior to hemodialysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with chronic kidney failure
Exclusion criteria: Patients with a history of glaucoma, uveitis, macular disease, retinal diseases; Patients who have had a history of eye surgery, retinal laser therapy and intravitreal injections for the past three months; Patients whose axial length is outside the range of 22 to 24 mm

Intervention groups

In the intervention group, the patient undergoes dialysis for 3 to 4 hours with a blood flow of 250 to 300 ml/min.

Main outcome variables

Retinal thickness; Choroidal thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N135**

Registration date: **2020-01-14, 1398/10/24**

Registration timing: **prospective**

Last update: **2020-01-14, 1398/10/24**

Update count: **0**

Registration date

2020-01-14, 1398/10/24

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

froughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-30, 1398/11/10

Expected recruitment end date

2020-05-30, 1399/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of hemodialysis on retinal and choroidal thickness in patients with chronic renal disease

who underwent hemodialysis in the dialysis ward of Imam Khomeini Hospital

Public title

The effect of hemodialysis on retinal and choroidal thickness in patients with chronic renal disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chronic kidney failure

Exclusion criteria:

Patients with a history of glaucoma, uveitis, macular disease, retinal diseases. Patients who have had a history of eye surgery, retinal laser therapy and intravitreal injections for the past three months. Patients whose axial length is outside the range of 22 to 24 mm.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 83

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly Individually by random number table via code reception

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2019-06-26, 1398/04/05

Ethics committee reference number

ir.kums.rec.1398.937

Health conditions studied

1

Description of health condition studied

Chronic renal failure

ICD-10 code

N18.1

ICD-10 code description

Chronic kidney disease, stage 1

Primary outcomes

1

Description

Retinal thickness

Timepoint

The beginning and the end of the study

Method of measurement

Using Optical coherence tomography (OCT)

2

Description

Choroidal thickness

Timepoint

The beginning and the end of the study

Method of measurement

Using Optical Coherence Tomography (OCT)

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, a complete eye examination is performed 30 minutes before the start of the study. Then the patient undergoes dialysis for 3 to 4 hours with a blood flow of 250 to 300 ml/min. After the end of the study, an eye examination is performed again and the effects of the intervention will be assessed before and after the study.

Category

Treatment - Other

2

Description

The control group will not receive any intervention

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Sasan Beyranvand

Street address

Street Naghliyah, Imam Khomeini Hospital

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6718743161

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

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fnajafi@kums.ac.ir

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Sasan Beyranvand

Position

Resident of Ophthalmology

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

Street address

Street Naghliyah, Imam Khomeini Hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Fariba Shaikhi Shoshtari

Position

Member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Resident of Ophthalmology

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

3 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

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

In a 15-day period, the documents will be sent e-mail

Comments