

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Investigation of hearing loss changes in ULTRAHIGH frequency in patients with chronic renal failure in terms of number of dialysis and duration of illness

Protocol summary

Study aim

Determination of hearing changes in ULTRAHIGH frequency in patients with chronic renal failure according to the number of dialysis sessions and the duration of the disease.

Design

Clinical trial without control group, with one group, without blinding, non-random, without phase on 20 patients

Settings and conduct

In this study, 20 patients under the age of 60 with chronic renal failure who are on dialysis in Khatam and Razavi hospitals of Shahroud and Damghan Velayat hospital are studied. Patients underwent pure tone audiometric (PTA) test twice. One hearing test is done before dialysis and the next time after 4 months.

Participants/Inclusion and exclusion criteria

Admission: Patients under 60 years of age with chronic renal failure undergoing dialysis. Absence: History of hearing loss due to exposure to loud noise, hereditary and genetic diseases of hearing loss, acquired hearing loss for any reason before referral, use of autotoxic drugs such as furosemide and aminoglycosides for more than a week, tinnitus Permanent, kidney transplant, chronic ear infection, mental disability

Intervention groups

20 patients with chronic renal failure undergoing dialysis undergo PTA at high frequencies (2000-8000 Hz) to assess their hearing changes

Main outcome variables

Hearing changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201112049369N1**

Registration date: **2020-12-22, 1399/10/02**

Registration timing: **retrospective**

Last update: **2020-12-22, 1399/10/02**

Update count: **0**

Registration date

2020-12-22, 1399/10/02

Registrant information

Name

Sanaz Koroji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4464 7153

Email address

dr.sanazkoroji@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

2020-07-22, 1399/05/01

Actual recruitment end date

2020-11-21, 1399/09/01

Trial completion date

2020-11-21, 1399/09/01

Scientific title

Investigation of hearing loss changes in ULTRAHIGH frequency in patients with chronic renal failure in terms of number of dialysis and duration of illness

Public title

Investigation of hearing loss changes in ULTRAHIGH frequency in patients with chronic renal failure

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with chronic renal failure under the age of 60 who are on dialysis

Exclusion criteria:

History of hearing loss following loud exposure Having inherited or genetic diseases of hearing loss Acquired hearing impairment for any reason before referral Taking autotoxic drugs such as furosemide and aminoglycosides for more than a week Having persistent tinnitus Kidney transplant Chronic ear infection intellectual disability

Age

To 60 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 20

Actual sample size reached: 20

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahroud Islamic Azad University of medical sciences

Street address

Shahroud Islamic Azad University, University blvd, Shahroud, Semnan

City

Shahroud

Province

Semnan

Postal code

43189-36199

Approval date

2020-01-15, 1398/10/25

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1398.063

Health conditions studied**1****Description of health condition studied**

Evaluation of hearing changes in patients with chronic renal failure undergoing dialysis

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Hearing changes in patients with chronic renal failure undergoing dialysis

Timepoint

Perform audiometry before dialysis at the beginning of the study and 4 months later

Method of measurement

Pure tone audiometry test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 20 patients with chronic renal failure under the age of 60 who are on dialysis under one period of pure tone audiometry (PTA) test at high frequencies (2000-8000Hz) at the beginning of the study before dialysis and the next time after 4 months Placed

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Khatam Shahroud Hospital

Full name of responsible person

Sanaz Koroji

Street address

Central dormitory of Islamic Azad University, University Blvd., Shahroud

City

Shahroud

Province

Semnan

Postal code

43189-36199

Phone
+98 23 3239 4536
Email
dr.sanazkoroji@gmail.com

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Recruitment center

Name of recruitment center
Velayat Damghan Hospital
Full name of responsible person
Sanaz Koroji
Street address
Central dormitory of Islamic Azad University,
University Blvd., Shahroud
City
Shahroud
Province
Semnan
Postal code
43189-36199
Phone
+98 23 3239 4536
Email
dr.sanazkoroji@gmail.com

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Recruitment center

Name of recruitment center
Razavi Shahroud Hospital
Full name of responsible person
Sanaz Koroji
Street address
Central dormitory of Islamic Azad University,
University Blvd., Shahroud
City
Shahroud
Province
Semnan
Postal code
43189-36199
Phone
+98 23 3239 4536
Email
dr.sanazkoroji@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Sanaz Koroji
Street address
Central dormitory of Islamic Azad University,
University Blvd., Shahroud
City
Shahroud
Province

Semnan
Postal code
43189-36199
Phone
+98 23 3239 4536
Email
dr.sanazkoroji@gmail.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
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
Islamic Azad University
Full name of responsible person
Sanaz Koroji
Position
medical student
Latest degree
A Level or less
Other areas of specialty/work
Public Health
Street address
Central dormitory of Shahroud Azad University,
University Blvd., Shahroud
City
Shahroud
Province
Semnan
Postal code
43189-36199
Phone
+98 23 3239 4536
Email
dr.sanazkoroji@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Sanaz Koroji
Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

Public Health

Street address

Central dormitory of Shahroud Azad University,
University Blvd., Shahroud

City

Shahroud

Province

Semnan

Postal code

43189-36199

Phone

+98 23 3239 4536

Email

dr.sanazkoroji@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Sanaz Koroji

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

Public Health

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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