

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the efficacy and safety of mirtazapine and hydroxyzine in the treatment of uremic pruritus in hemodialysis patients: A randomized, double-blind controlled clinical trial

Protocol summary

Study aim

Comparison of the efficacy and safety of mirtazapine and hydroxyzine in the treatment of uremic pruritus in hemodialysis patients

Design

Clinical trial with control group, parallel groups, double-blind, block randomization, phase 2-3 on 60 patients

Settings and conduct

30 eligible patients in each group in Shahrvand renal center in Sari Mirtazapine 7.5 mg in the first two nights and then 15 mg at bedtime, with hydroxyzine placebo or hydroxyzine 12.5 mg in the first two nights and then 25 mg at bedtime, with mirtazapine placebo for 2 weeks. Placebo from the manufacturer or preparation of similar capsules of medicine and placebo by another person Blinding of treating physician, patient and evaluator student

Participants/Inclusion and exclusion criteria

Inclusion: age older than 18 years Hemodialysis for at least 3 months and itch despite the adequacy of hemodialysis 5D-itch above 5 PSQI equal and above 5
Exclusion: Hemoglobin less than 7 g/dl iPTH above 600 Phosphorus higher than 6 mg/dl and calcium higher than 10.5 mg/dl Chronic skin diseases with itching not related to uremia Chronic liver failure Untreated hypothyroidism Psychiatric disorders or any psychotropic medication use during the past month Suicide or suicidal ideation Inability to receive oral medication Use of corticosteroids and opium Pregnancy and lactation History of allergy to mirtazapine Receive medication which using for sleep disorders treatment within 1 month before entering the study No interest to participate in the study or continue to treatment Studied drugs intolerance

Intervention groups

Intervention: Mirtazapine 7.5 mg in the first two nights and then 15 mg at bedtime, along with hydroxyzine placebo for 2 weeks Control: Hydroxyzine 12.5 mg in the

first two nights and then 25 mg at bedtime, along with Mirtazapine placebo for 2 weeks

Main outcome variables

Changes of itch Intensity using 5D-itch criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120314009297N9**

Registration date: **2024-02-24, 1402/12/05**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-24, 1402/12/05**

Update count: **0**

Registration date

2024-02-24, 1402/12/05

Registrant information

Name

narjes hendouei

Name of organization / entity

mazandaran university of medical science

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and safety of mirtazapine and hydroxyzine in the treatment of uremic pruritus in hemodialysis patients: A randomized, double-blind controlled clinical trial

Public title

Effect of mirtazapine on pruritus in dialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age older than 18 years Hemodialysis for at least 3 months and having itch despite the adequacy of hemodialysis ($Kt/V > 1.2$) 5D-itch score more than 5 PSQI score equal and above 5

Exclusion criteria:

Anemia (Hemoglobin less than 7 g/dL)
Hyperparathyroidism (iPTH > 600) Phosphorus level higher than 6 mg/dL and calcium higher than 10.5 mg/dL, or calcium multiplied by phosphorus higher than 60 Chronic skin diseases with itching which not related to uremia caused by kidney failure, such as psoriasis, dermatitis, and lichen planus. Chronic liver failure or high bilirubin level (1.5 times higher than the upper limit of normal) , and ALT, AST more than 5 times higher than the upper limit of normal. Untreated hypothyroidism Patients with psychiatric disorders, such as bipolar disorder, mental retardation, cognitive-functional disorder, or use of any psychotropic medication during the past month. History of suicide or patients with suicidal ideation Inability to receive oral medication Use of corticosteroids and opium Pregnancy and lactation History of allergy to mirtazapine Receiving medications that used for sleep disorders treatment within 1 month before entering the study (such as tricyclic antidepressants, atypical antidepressants, benzodiazepines, antihistamines, anticholinergics, and barbiturates) No interest to participate in the study or continue to treatment Any complications leading to intolerance and discontinuation of treatment with studied drugs

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are placed in the intervention and control groups (with 1:1 ratio) based on a random block. The supervisor will perform randomization by using a random numbers table and assignment of 4-digit codes in both groups. The drugs and placebo will be placed in separate packages. The patient, the physician and the student (Clinical pharmacy resident) will be blind in this study. At the end of the study, the codes will be broken for statistical analysis.

Blinding (investigator's opinion)

Double blinded

Blinding description

Preparation of placebo from the manufacturing company or preparation of similar capsules of drug and placebo by someone outside the study. The attending physician, patient and evaluator student will be blinded.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Mazandaran University of Medical Sciences

Street address

Building No 2, Mazandaran University of Medical Sciences, Moallem Square, Sari, Iran

City

Sari

Province

Mazandaran

Postal code

۳۳۹۷۱-۴۸۱۵۷

Approval date

2023-10-25, 1402/08/03

Ethics committee reference number

IR.MAZUMS.REC.1402.455

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

Uremic pruritus

ICD-10 code

L29.9

ICD-10 code description

Pruritus, unspecified

Primary outcomes

1

Description

Changes of itch Intensity using 5D-itch criteria

Timepoint

Baseline and the end of second, third and fourth weeks of starting the drug

Method of measurement

5D-itch checklist

Secondary outcomes

1

Description

Sleep quality changes based on the PSQI criterion

Timepoint

Baseline and the end of second, third and fourth weeks of starting the drug

Method of measurement

PSQI checklist

2

Description

Evaluation safety of the studied drugs

Timepoint

The end of the first, second and third weeks of starting the drug

Method of measurement

ASEC checklist

Intervention groups

1

Description

Intervention group: Mirtazapine tablets 7.5 mg (half a 15 mg tablet) in the first two nights and 15 mg (a whole tablet) from the third night at bedtime, along with hydroxyzine placebo for 2 weeks

Category

Treatment - Drugs

2

Description

Control group: Hydroxyzine tablets 12.5 mg (half a 25 mg tablet) in the first two nights and 25 mg (a whole tablet) from the third night at bedtime, along with Mirtazapine placebo for 2 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrvand dialysis Center in Sari

Full name of responsible person

Narjes Hendouei

Street address

No. 44 Keshavarz, Keshavarz Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Pedram Ebrahimnejad

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Narjes Hendouei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Clinical pharmacy

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Latest degree

Specialist

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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