Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 then15 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
Street address
Moallem street, Moallem square-Vice chancellor for research
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Fax
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pajhooheshi@mazums.ac.ir
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
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Person responsible for updating data

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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