

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of oral Mirtazapine and oral Gabapentin in treatment of uremic pruritus in hemodialysis patients

Protocol summary

Study aim

The purpose of this study is evaluation and comparison of oral gabapentin and oral mirtazapine in management of uremic pruritus in dialysis patients suffering from chronic kidney disease.

Design

cross-over clinical trial, community-based and pragmatic, simple randomization, The sample volume is 60 people

Settings and conduct

This study was performed as a clinical, cross-over, on hemodialysis patient referring to Nephrology and Dialysis ward of Shahid-Beheshti Hospital and Besat Hospital of Hamadan.

Participants/Inclusion and exclusion criteria

Entrance criteria: aged over 18 years old, diagnosis of the end stage of kidney disease, who receive 3 times daily dialysis and suffer from moderate, severe or very severe uremic itching. Exit criteria: hyperphosphatemia, diabetic neuropathy, patients with psychiatric disorders Not able to cooperate.

Intervention groups

Intervention group 1: Patients receive oral 15 mg mirtazapine daily once a week for two weeks, and after two weeks of study and one week of purification, patients undergoing treatment with mirtazapine for two weeks are treated with gabapentin. The intervention group 2 :In gabapentin group, 100 mg of oral gabapentin is taken once daily for up to two weeks each day. After two weeks of study and a week of cleansing, gabapentin groups are treated with mirtazapine for two weeks.

Main outcome variables

Severity of itching in patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150629022965N20**

Registration date: **2018-09-18, 1397/06/27**

Registration timing: **retrospective**

Last update: **2018-09-18, 1397/06/27**

Update count: **0**

Registration date

2018-09-18, 1397/06/27

Registrant information

Name

Maryam Mehrpooya

Name of organization / entity

School of Pharmacy, Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral Mirtazapine and oral Gabapentin in treatment of uremic pruritus in hemodialysis patients

Public title

Effects of mirtazapine and gabapentin in treatment of uremic pruritus

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
aged above 18 diagnosis of end stage renal disease receiving dialysis 3 times a week no history of dermatological disorder which result in feeling itch no history allergen medications or foods no history of receiving medication which relieve itch presence of moderate, severe and very severe pruritus
Exclusion criteria:
pregnancy or lactation presence of liver failure presence of any psychiatric disorder hyperphosphatemia diabetic neuropathy

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are placed in the intervention group or control group by simple randomization method by sealed envelope.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, In front of Luna park, Pazhouhesh Cross , Hamadan

City

Hamadan

Province

Hamadan

Postal code

6517619651

Approval date

2017-12-20, 1396/09/29

Ethics committee reference number

IR.UMSHA.REC.1396.622

Health conditions studied

1

Description of health condition studied

Chronic kidney disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes

1

Description

severity of pruritus based on Visual analogue scale

Timepoint

daily for 5 weeks

Method of measurement

Visual analogue scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients were given 14 day, 15 mg once a day tablet of mirtazapine, from the company Schering-Plow, to prescribe uremic urea. After one week of washing, patients treated with 100 mg gabapentin daily will receive 14 days from Iran daroo, Iran.

Category

Treatment - Drugs

2

Description

Control group: Gabapentin is given 100 mg orally once a day for two weeks After a washout week, patients were given , 15 mg tablet of mirtazapine once a day,for 14 days , purchased from the company Schering-Plow Myrazapine, to control the uremic pruritus.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital of Hamadan

Full name of responsible person
Dr Mahmood Gholiaf
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Sponsors / Funding sources

1

Sponsor

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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

Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person

Maryam Mehrpooya
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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