Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effects of mirtazapin on serum levels of histamin and serotonin in hemodialysis Patients suffering from uremic pruritus

Protocol summary

Study aim
The purpose of this study is evaluation of the effects of oral mirtazapine on serum level of histamine and serotonin in dialysis patients suffering from chronic kidney disease.

Design
Clinical practice, non-control group, community based and pragmatic, 38 patients were evaluated before intervention and then intervention.

Settings and conduct
This study will be performed as a clinical trial before and after on patients receiving hemodialysis referring to the Department of Nephrology and Dialysis in Shahid Beheshti Hospital and Besat Hospital in Hamedan.

Participants/Inclusion and exclusion criteria
inclusion criteria:aged above 18 years old,diagnosis of end stage renal disease who receive dialysis 3 times a week with moderate, severe and very severe uremic pruritus.exclusion criteria:Hyperphosphatemia, diabetic neuropathy, and patients who are unable to work due to psychiatric disorders.

Intervention groups
Patients will receive 7.5 mg/day mirtazapine for two weeks.

Main outcome variables
Serum level of histamine and serotonin

General information

Reason for update

Acronym
-

IRCT registration information
IRCT registration number: **IRCT20150629022965N18**
Registration date: **2018-08-04, 1397/05/13**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-04, 1397/05/13**
Update count: **0**

Registration date
2018-08-04, 1397/05/13

Registrant information

Name
Maryam Mehrpooya

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School of Pharmacy,Hamadan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2018-08-23, 1397/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effects of mirtazapin on serum levels of histamin and serotonin in hemodialysis Patients suffering from uremic pruritus

Public title
Effects of mirtazapine on serum levels of histamin and serotonin

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: **30**

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 the 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

2018-02-24, 1396/12/05

Ethics committee reference number

IR.UMSHA.REC.1396.819

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

Serum level of histamine

Timepoint

at baseline and 14 days later

Method of measurement

ELISA kit

2

Description

Serum level of serotonin

Timepoint

at baseline and 14 days later

Method of measurement

ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: mirtazapine, 7.5 mg/day, for 14 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital of Hamadan

Full name of responsible person

Vida Sheikh

Street address

Shahid Beheshti Hospital, Eram Blvd, Hamadan, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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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

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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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