Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison between Pregabalin and Sertraline for treatment of Uremic Pruritus

Protocol summary

Study aim
To compare the efficacy of pregabalin and sertraline in treating uremic pruritus
Design
Randomized clinical trial
Settings and conduct
This single-center clinical trial would be conducted at the Pak Emirates Military Hospital (Dialysis Unit). All patients to provide consent. Patients to be randomized to receive either Pregabalin or Sertraline. Urdu version of the 5-D Itch Scale would be self-administered to assess severity of itching at baseline, and at 6 weeks post commencement of treatment.
Participants/Inclusion and exclusion criteria
Patients of both genders having age ≥19 years, on twice weekly HD for ESRD for at least six months, and having UP for at least six weeks, were included in this study. Exclusion criteria included dermatological or systemic diseases associated with pruritis, mental health issues affecting the ability to respond to the 5-D Itch Scale, and patients on a thrice-a-week HD schedule. Moreover, individuals already on some treatment for UP were generally excluded, except for patients on oral anti-histamines, for whom there was a washout period of two weeks before participation in this study
Intervention groups
The Pregabalin group would be given Pregabalin 75mg once a day orlly, while Sertraline Group would be given sertraline 50mg once a day orally.
Main outcome variables
Change in the severity of pruritus after six weeks of intervention.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240208060941N1**
Registration date: **2024-02-14, 1402/11/25**
Registration timing: **retrospective**

Last update: **2024-02-14, 1402/11/25**
Update count: **0**
Registration date
2024-02-14, 1402/11/25

Registrant information
Name
Muhammad Iqbal
Name of organization / entity
Pak Emirates Military Hospital/ National University of Medical Sciences
Country
Pakistan
Phone
+92 342 7007463
Email address
iqbalkharal2934@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-10-01, 1402/07/09
Expected recruitment end date
2023-12-01, 1402/09/10
Actual recruitment start date
2023-10-06, 1402/07/14
Actual recruitment end date
2023-12-13, 1402/09/22
Trial completion date
2024-01-31, 1402/11/11

Scientific title
Comparison between Pregabalin and Sertraline for treatment of Uremic Pruritus

Public title

Comparison between Pregabalin and Sertraline for treatment of itching in kidney failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients from both genders greater than 18 years of age Patients on twice weekly hemodialysis for at least 6 months Patients having uremic pruritus for more than 6 weeks

Exclusion criteria:

Patients with dermatological or systemic diseases associated with pruritis (such as acute hepatitis, chronic liver disease, pregnancy, and hypothyroidism) Patients with mental health issues affecting their ability to respond to the 5-D Itch Scale (such as psychosis, obsessive-compulsive disorder, or substance abuse) Patients on thrice-a-week haemodialysis schedule Not consenting to participate

Age

From **19 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **46**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done using computer generated sequences, prepared online

Blinding (investigator's opinion)

Single blinded

Blinding description

The 5-D itch Scale questionnaire would be self-administered, but the first author of this study would be available to answer patients' queries and to ensure that there was is missing data on these forms. He would remain blinded to treatment being given.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Comittee Pak Emirates Military Hospital Rawalpindi

Street address

Pak Emirates Military Hospital, Mall Road

City

Rawalpindi

Postal code

46000

Approval date

2023-05-10, 1402/02/20

Ethics committee reference number

A/28/EC/535/23

Health conditions studied

1

Description of health condition studied

end stage renal disease

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

Primary outcomes

1

Description

Change in severity of pruritis

Timepoint

6 weeks post initiation of treatment

Method of measurement

The 5-D Itch Scale (Urdu version)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Pregabalin group

Category

Treatment - Drugs

2

Description

Intervention group 2: Sertraline group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pak Emirates Military Hospital Rawalpindi

Full name of responsible person

Muhammad Iqbal
Street address
Pak Emirates Military Hospital, Abid Majeed Road
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pak Emirates Military Hospital
Full name of responsible person
Muhammad Iqbal
Street address
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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
Pak Emirates Military Hospital
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
Pak Emirates Military Hospital
Full name of responsible person
Muhammad Iqbal
Position
Registrar Medicine
Latest degree
Medical doctor
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)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The Deidentified Individual Participant Data Set, Study Protocol, Statistical Analysis Plan, and Informed Consent forms will be made available to desirous researchers upon reasonable requests, and after clearance from the institutional data registry body. The said documents will be shared in a non-editable format via email after scrutinizing the need for subject documents by the requesting authorities.

When the data will become available and for how long

The above-mentioned documents will be available after December 2024 for 10 years as per institutional data registry protocols.

To whom data/document is available

The data will be available only for non-commercial research purposes and will be provided to academic institutions only.

Under which criteria data/document could be used

The data/ document can be used for literary and non-commercial purposes.

From where data/document is obtainable

The Data can be obtained via email from: Dr Muhammad Iqbal Department of Medicine, Pak Emirates Military Hospital, Abid Majeed Road, Rawalpindi, Punjab, Pakistan, 46000. Email: iqbalkharal2934@gmail.com

What processes are involved for a request to access data/document

Data requests can be directly made to Dr Muhammad Iqbal via email provided earlier. After the request is received, it will submitted to the Institutional Data Control and Registry Committee for necessary verification and clearance of the requested documents. Any additional information required by the committee will be forwarded to the requestee via email. After satisfying requirements of the Institutional Data Control and Registry Committee, the requested data/ documents will shared with the requesting person via suitable means. This process may take up to 6 weeks from the date of reception of the request.

Comments