Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparison the effect of ondansetron and placebo on pruritus in hemodialysis patients

Protocol summary

Summary

Pruritus is the most distressing symptom in haemodialysis patients. Its aetiology has not yet been delineated, and thus there are no good therapeutical options. Serotonin has been reported to be a mediator of uremic pruritus, and ondansetron is a potent and selective inhibitor of 5-HT3 receptors. The aim of our study was to evaluate the effect of ondansetron on uremic pruritus in haemodialysis patients. All patients undergoing haemodialysis at the dialysis unit in Valiasr Hospital were asked to complete a questionnaire about pruritus .Pruritus scores were distinguished by a visual analogue scale (VAS) system between 0 and 10 and recorded for 2 weeks twice a day (morning and evening). Patients with pruritus score more than 4 were considered for inclusion. Criteria for exclusion of patients from the study included age less than 18 years, patients with a history of skin or metabolic disease causing itching, patients who received ani-pruritic medications two weeks before, pregnant women and non-cooperation patients. The final analysis included 70 patients. They were randomly divided into two groups: one group, ondansetron 8 mg three times daily and the other group was given loratadine (placebo) 10 mg two times a day for 2 week and pruritus scores were recorded by the patients. The mean scores were compared before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111288241N1**
Registration date: **2013-02-21, 1391/12/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-02-21, 1391/12/03

Registrant information

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Mina Mirnezami
Name of organization / entity
Arak University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and education of Arak University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2010-11-21, 1389/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of ondansetron and placebo on pruritus in hemodialysis patients

Public title

Effect of ondansetron on pruritus in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with chronic renal failure undergoing hemodialysis; willingness of patients for entry into the study; minimum age 18 years. Exclusion criteria: Patients with a history of skin or metabolic disease causing itching; Patients who received anti-pruritic medications two weeks before; pregnant women; People under age 18; non-cooperation Patients.

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Arak University of Medical Sciences

Street address
University of Medical sciences' Arak

City
Arak

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
89-81-7

Health conditions studied

1

Description of health condition studied
Chronic renal failure

ICD-10 code
N17-N19

ICD-10 code description
Renal failure

Primary outcomes

1

Description
Pruritus

Timepoint
Baseline - A week later, two weeks after the intervention.

Method of measurement
VAS

Secondary outcomes

1

Description
Side effect

Timepoint
During the intervention

Method of measurement
Visual and laboratory

Intervention groups

1

Description
Ondansetron tablets 8 mg three times daily for two weeks in the intervention group

Category
Treatment - Drugs

2

Description
Loratadine tablets 10 mg twice daily in the control group

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr Medical Center Hemodialysis Unit, Arak

Full name of responsible person
Dr. Mina Mirnezami

Street address
Valiasr Hospital

City
Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research and education

Full name of responsible person

Dr. Changizi Ashtiani

Street address

Vice chancellor for research and education, Basij Square

City

Arak

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research and education

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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Diploma of Dermatology/Assistant Professore

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty