Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Investigation of antipruritic effect of oral nicotinamide in uremic patients

Protocol summary

Summary

The study employed a randomized, comparative, doubled-blind design. Randomization was performed by using a random number table, and the patients (50 known cases of end-stage renal disease treated with hemodialysis, aged 18-60 years) were randomly allocated to one of the two arms of the study: study group (oral nicotinamide 500 mg two times a day) or control group (placebo). The placebo was formulated by a pharmacist to have similar base with the drug but not containing the active ingredient. The same tablet to make both tablets to look physically identical. The used medications were not revealed to their physicians. The patients instructed to drink the medication two times a day for 4 week and were prohibited to use any other treatments for pruritus during the study but they were allowed to use their routine medications, e.g. antihypertensive agents. Each Patient was visited five times in total, one time at the beginning of treatment and weekly for one month. At each visit patients were oriented on how to interpret their pruritus based on Visual Analogue Scale (VAS) (0: no pruritus and 5: the worst pruritus).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202068940N1**
Registration date: **2012-04-13, 1391/01/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-04-13, 1391/01/25

Registrant information

Name

Ahmad Khazanee

Name of organization / entity

Jundishapur University of Medical Sciences

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Iran (Islamic Republic of)

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+98 61 1336 2535

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Recruitment status

Recruitment complete

Funding source

Jundishapur University of Medical Sciences

Expected recruitment start date

2011-06-22, 1390/04/01

Expected recruitment end date

2011-07-21, 1390/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of antipruritic effect of oral nicotinamide in uremic patients

Public title

Investigation of antipruritic effect of oral nicotinamide in uremic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: known cases of end-stage renal disease patients treated with hemodialysis; ages between 18 and 60 years; At least 6 weeks history of pruritus; no systemic or topical treatment for the pruritus. Exclusion criteria: a known hypersensitivity to nicotinamide; suffering from other known skin diseases, liver disorders, metabolic disorders, any other condition except for CRD causing pruritus; any serious systemic

disease; Usage of antihistamines or other anti-pruritus drugs in the last three months.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

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
Jundishapur University of Medical Sciences

Street address
Ahvaz Jundishapur University of Medical Sciences

City
Ahvaz

Postal code

Approval date
2011-01-03, 1389/10/13

Ethics committee reference number
ETH-112

Health conditions studied

1

Description of health condition studied
Uremic pruritus

ICD-10 code
C00-D48

ICD-10 code description
Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified

Primary outcomes

1

Description
Attenuation of uremic pruritus

Timepoint
Four weeks

Method of measurement
By using a traditional Visual Analogue Scale (VAS) and a modified questionnaire method (pruritus score)

Secondary outcomes

empty

Intervention groups

1

Description
placebo

Category
Placebo

2

Description
oral nicotinamide 500 mg two times a day

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dialysis Ward, Ahvaz Imam Hospital

Full name of responsible person
Ahmad Khazanee

Street address
Imam Hospital, Jundishapur University of Medical Sciences

City
Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Jundishapur University of Medical Sciences

Full name of responsible person
Mostafa Feghhi

Street address
Jundishapur University of Medical Sciences

City
Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Jundishapur University of Medical Sciences

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

Jundishapur University of Medical Sciences

Full name of responsible person

Ahmad Khazanee

Position

Resident of Dermatology

Other areas of specialty/work

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Person responsible for updating data

Contact

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