Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Trial comparison of the effect of cutaneous lipogels containing Jujube and Echium amoenum plant extracts with placebo on the severity of pruritus in hemodialysis patients.

Protocol summary

Study aim
Determining the effect of cutaneous lipogels containing jujube and Echium extracts in comparison with placebo on the severity of pruritus in hemodialysis patients

Design
Phase 3 randomized double-blind crossover clinical trial on 50 patients. Randomization Blocked permutation method was used for randomization and there will be 8 blocks of size 6 and one block of size 2.

Settings and conduct
This study is double-blind in which the researcher who evaluates the pruritus and also the patients do not know the content of the drug tube and only the pharmacist knows the content of the tube. Place of study: Sari Shahrvand dialysis center and dialysis ward of Sari Fatemeh Zahra hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Hemodialysis patients over 18 years of age who undergo dialysis twice a week; Moderate to severe pruritus according to the Jusipovich ISS pruritus questionnaire in the last two weeks; parathyroid hormone less than 300 and phosphorus less than 6. Non-inclusion criteria: presence of wound; Generalized limb edema (more than one plus (+1); allergy or sensitivity while working; pregnancy; breastfeeding

Intervention groups
Intervention group: Drug group (lipogel containing jujube and borage extracts). Control group: placebo group (lipogel without drug extract)

Main outcome variables
pruritus severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110906007494N33**
Registration date: **2020-09-15, 1399/06/25**
Registration timing: **prospective**

Last update: **2020-09-15, 1399/06/25**
Update count: **0**

Registration date
2020-09-15, 1399/06/25

Registrant information

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Name of organization / entity
Mazandaran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-11, 1399/07/20

Expected recruitment end date
2020-12-25, 1399/10/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Trial comparison of the effect of cutaneous lipogels containing Jujube and Echium amoenum plant extracts

with placebo on the severity of pruritus in hemodialysis patients.

Public title
The Effect of topical lipogel containing herbal extracts of Ziziphus jujuba and Echium amoenum on pruritus severity in hemodialysis patient
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Hemodialysis patients aged 18 years and older End-stage renal disease undergoing regular dialysis treatment at least two or three times a week for six months Having itching in the last two weeks and having an itching intensity score using the Usipovich Itching Intensity Scale (ISS) in the range of severe and moderate pruritus Full alertness and ability to communicate Parathyroid hormone (PTH), <300 Phosphor(P) <6
Exclusion criteria:
Existence of wounds in the limbs Generalized limb edema (more than one plus (+1) Pregnancy Breastfeeding Other chronic diseases and cancer Taking other topical medications and antihistamines History of any allergies (skin, especially to plant compounds)
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible patients will be randomly divided into two groups, group A and group B, using random number generation and computer software. With the computer program, the Randomization Blocked permuation method is applied and random blocks will be selected so that we will have 8 blocks of size 6 and one block of size 2. The patient number will be recorded on the medicine can.
Blinding (investigator's opinion)
Double blinded
Blinding description
The researcher who evaluates the pruritus and also the patients do not know the contents of the medicine cans, only the pharmacist knows the contents of the cans.
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
Vice chancellor for research, No 2 building, Mazandran University of Medical Sciences, Moalem street, Moalem square
City
Sari
Province
Mazandaran
Postal code
4816715793
Approval date
2020-07-21, 1399/04/31
Ethics committee reference number
IR.MAZUMS.REC.1399.474

Health conditions studied

1

Description of health condition studied
Pruritus in hemodialysis patients
ICD-10 code
L29.9
ICD-10 code description
Pruritus, unspecified

Primary outcomes

1

Description
Pruritus
Timepoint
The first visit; the first, second, third and fourth weeks after starting to use lipogels.
Method of measurement
Itching 48-point scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Due to the fact that the study is a cross-over method, there are 25 people in each group. A group of 25 people with jujube and Echium amoenum lipogel will be replaced with a lipogel and placebo group after a two-week wash out period. Patients by unit FTU (one (FTU) is equal to the index finger to the first finger joint, lipogel removed from the tube with a diameter of

0.5 cm depending on the level of itching twice a day (morning (9 am) - night) 9 nights) so that a thin layer of lipogel is rubbed and spread on the itchy area of the body for one minute and the amount of medicine used on each part of the body is recorded based on the fingerprint scale. The drug is stopped for two weeks for washout.

Category

Treatment - Drugs

2

Description

Control group: Patients who received placebo in the first stage of the drug (Ziziphus jujuba and Echium amoenum) and the group who received the drug are given placebo and again patients in terms of severity of pruritus, distribution of pruritus and drug side effects for one week and up to four per week The following week, they are examined during a telephone call with patients.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Zahra Hospital, Sari

Full name of responsible person

Azam faraji

Street address

Mazandaran University of Medical Sciences; Juibar tree way

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2

Recruitment center

Name of recruitment center

Shahrvand center; Sari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr.Majid Saeedi

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Grant name

Grant code / Reference number

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

No

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr.Masoumeh Bagheri Nesami

Position

PhD. Nursing Education

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
no more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not 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
No - There is not a plan to make this available