

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Trial comparison of the effect of cutaneous lipogels containing Jujube and Echim 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 Echim 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

###### Name

Masoumeh Bagheri Nesami

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3336 7551

###### Email address

mbagheri@mazums.ac.ir

##### 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 Echim 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 permutation 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

##### City

Sari

##### Province

Mazandaran

##### Postal code

4815733971

##### Phone

+98 11 3565 2616

##### Fax

##### Email

Az\_faraji200@yahoo.com

##### Web page address

### 2

#### Recruitment center

##### Name of recruitment center

Shahrvand center; Sari

##### Full name of responsible person

Azam faraji

##### Street address

Mazandaran University of Medical Sciences; Juibar tree way

##### City

Sari

##### Province

Mazandaran

##### Postal code

4815733971

##### Phone

+98 11 3565 2616

##### Email

Az\_faraji200@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Dr.Majid Saeedi

##### Street address

Mazandaran University of Medical Sciences; Joybar threeway; Valiyeasr highway; Imam square

##### City

Sari

##### Province

Mazandaran

##### Postal code

4815733971

##### Phone

+98 11 3565 2616

##### Email

az\_faraji200@yahoo.com

##### 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

##### Street address

Vice chancellor for research, No 2 building,  
Mazandran University of Medical Sciences, Moalem  
street, Moalem square

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815733971

**Phone**

+98 11 3565 2616

**Email**

az\_faraji200@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Masoume Bagheri Nesami

**Position**

Nursing ph.D

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Mazandaran University of Medical Sciences, Basij  
highway, Joibar three way, Imam square

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816715793

**Phone**

+98 11 3565 2616

**Email**

az\_faraji200@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr.Masoumeh Bagheri Nesami

**Position**

ph.D. Nursing Education

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Research Assistant of Mazandaran University of  
Medical Sciences

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815733971

**Phone**

+98 11 3565 2008

**Email**

az\_faraji200@yahoo.com

## 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