Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Sambucus ebulus topical preparation and placebo, on pruritus in hyperuremic patients, a clinical trial

Protocol summary

Summary

The aim of this clinical study is to compare the effect of Sambucus ebolus extract topical preparation and placebo, on hyper uremic pruritus. The patients who are suffering from severe pruritus due to renal failure are included in this study. Thirty patients in intervention group will receive Sambucus ebolus topical preparation and the 30 patients in the control group will receive placebo. Patients are randomly allocated to the intervention and control group. Randomization will be performed using random number table. The prescriber and evaluator will be blind during the study. The study will be done in one center. All of the renal failure patients with hyper uremic pruritus (men or women) will be included in this study and every one with sensitivity to topical preparation will be excluded. The patients will receive topical preparation (Sambucus ebulus topical preparation or placebo) twice a day for two months and the pruritus severity index and other symptoms such as dryness and ulceration due to scratching will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102810203N7**
Registration date: **2017-03-16, 1395/12/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-03-16, 1395/12/26

Registrant information

Name

Majid Saeedi

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1354 3082

Email address

msaeedi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Sambucus ebulus topical preparation and placebo, on pruritus in hyperuremic patients, a clinical trial

Public title

Evaluation of Palem topical preparation on hemodialysis pruritus

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with hemodialysis during 3 months, or chronic renal failure with hyperuremia; at the age of 18 years and more; 3 times pruritus during last two weeks before study; dry skin without edema.
Exclusion criteria: Other diseases like liver failure and

heart disease; pregnancy and breast feeding; sensitivity to topical preparation.

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Random numbers table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences

Street address
Moallem sq.

City
Sari

Postal code

Approval date
2015-11-21, 1394/08/30

Ethics committee reference number
IR.MAZUMS.REC.94-1785

Health conditions studied

1

Description of health condition studied
hyperuremic pruritus

ICD-10 code
L29.9

ICD-10 code description
Pruritus, unspecified

Primary outcomes

1

Description
Pruritus severity

Timepoint
Baseline, 4th and 8th week

Method of measurement
Pruritus severity scale (48 scores)

Secondary outcomes

1

Description
Skin Xerosis

Timepoint
Baseline, 4th and 8th weeks

Method of measurement
observation

Intervention groups

1

Description
Control group: Placebo, two times a day for two months

Category
Placebo

2

Description
Intervention group: Sambucus ebulus topical preparation 2% , two times a day for two months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Boo Ali hospital

Full name of responsible person
Majid Saeedi

Street address
Pasdaran Blvd, Sari

City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person
Prof. Ahmad Ali Enayati

Street address

Moallem Sq.

City

Sari

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, Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Position

Pharmaceutics, Professor

Other areas of specialty/work

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Name of organization / entity

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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