

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of locally administered Sambucus ebulus gel 5% on the severity and extention of pruritus in hemodialysis patients

Protocol summary

Study aim

Comparison of the effect of topical gel containing Sambucus ebulus extract compared with placebo on reducing itching complications in hemodialysis patients

Design

A randomized, controlled, single-blind, placebo-controlled clinical trial

Settings and conduct

A randomized, controlled, single-blind, placebo-controlled clinical trial The person evaluating the severity of the itch is unaware of the product The dialysis centers of the citizens of Sari and Imam Reza Amol are performed. The sample size is 150 patients. The person evaluating the severity of the itch is unaware of the product. Due to the special color and smell of herbal products, it is not possible to blind the patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 18 years who have been undergoing hemodialysis for more than 3 months, Patients who have had itching at least 3 times in the last 2 weeks, Despite drug use in the last month of treatment, no evidence of improvement was observed, Patients undergo hemodialysis 3 days a week for 3-5 hours per session, Have no skin problems other than uremic itching, Patients who gave their written consent to participate in the project, Patients who do not use another method to reduce their severity, Lack of systemic diseases such as liver cholestatic, hepatitis B, HIV thyroid disorders and women who are not pregnant and breastfeeding, Lack of cognitive impairments that cannot answer questions, Exclusion criteria: If the patient undergoes kidney transplantation during the study, If allergic to sambucus ebulus gel, Patients who do not wish to continue the study for personal reasons, Patients suffering from P tests above 6 and PTH more than 300

Intervention groups

Group A: sambucus ebulus gel, Group B: Placebo gel, Group C: Control (without intervention)

Main outcome variables

pruritus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191231045958N1**

Registration date: **2020-04-12, 1399/01/24**

Registration timing: **prospective**

Last update: **2020-04-12, 1399/01/24**

Update count: **0**

Registration date

2020-04-12, 1399/01/24

Registrant information

Name

Mohadese Saberian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4466 9545

Email address

h_saberian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of locally administered Sambucus ebulus gel 5% on the severity and extention of pruritus in hemodialysis patients

Public title

The effect of locally administered Sambucus ebulus gel 5% on the severity and extention of pruritus in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 18 years who have been undergoing hemodialysis for more than 3 months Patients who have had itching at least 3 times in the last 2 weeks Despite drug use in the last month of treatment, no evidence of improvement was observed Patients undergo hemodialysis 3 days a week for 3-5 hours per session Have no skin problems other than uremic itching Patients who gave their written consent to participate in the project Patients who do not use another method to reduce the severity of itching Lack of systemic diseases such as liver cholestatic, hepatitis B, HIV thyroid disorders and women who are not pregnant and breastfeeding Lack of cognitive impairments that cannot answer questions

Exclusion criteria:

If the patient undergoes kidney transplantation during the study If there is allergy to sambucus ebulus gel Patients who do not wish to continue the study for personal reasons Patients with a phosphorus test range of more than 6 and a PTH of more than 300

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to each group using Permuted block Randomization as follows. We select 25 blocks of 6. The blocks will be from 120 different modes such as AABBC, AABCBC, AACBCB, ABCABC, BABCAC, ACBBCA. In each block there will be two cases of group A and two cases of group B and two cases of group C. The computer program selects one randomly each time and the order of people in the groups is random.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person evaluating the severity of the itch is an unaware product

Placebo

Used

Assignment

Parallel

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

Moalem Square

City

Sari

Province

Mazandaran

Postal code

48175886

Approval date

2020-03-11, 1398/12/21

Ethics committee reference number

IR.MAZUMS..REC.1398.6082

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

first visit-The fourth and eighth week after starting to use the gel.

Method of measurement

48-point scale for itching severity

Secondary outcomes

1

Description

skin dryness

Timepoint

first week, The fourth and eighth week after starting to use the gel.

Method of measurement

Examination

Intervention groups

1

Description

The aim of this study was to investigate the effect of locally administered sambucus ebulus gel 5% on the severity and extention of pruritus hemodialysis patients. Three groups of patients are examined, in each group there are 50 hemodialysis patients. The first group uses sambucus ebulus 5% gel - the second group uses placebo gel and the third group is without intervention. sambucus ebulus gel prepared in the laboratory of Mazandaran University of Medical Sciences .After preparing the gel, Patients in both the intervention and placebo groups are taught to use the gel twice a day, morning and night, for 8 weeks. So as to cover the itchy area. Intervention group: Topical product containing 5% sambucus ebulus extract, twice daily for two months

Category

Treatment - Drugs

2

Description

Control group: placebo gel. Fifty hemodialysis patients who are randomly assigned to this group use placebo gel prepared at the Faculty of Pharmacy, Mazandaran University. These patients are also taught to use the gel twice a day, morning and night, at home for 8 weeks to cover the itchy area.

Category

Placebo

3

Description

Without intervention-This group was considered for the psychological dimension of drug use in patients with severe itching.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza (AS) Amol City Hospital

Full name of responsible person

hedayat jafari

Street address

Imam Reza Boulevard

City

Amol

Province

Mazandaran

Postal code

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Phone

+98 11 4327 4013

Email

hedayat2003@yahoo.com

2

Recruitment center

Name of recruitment center

Shahrvand

Full name of responsible person

Hedayat jafari

Street address

Keshavarz Boulevard

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4815733971

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+98 11 3329 1897

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hedayat2003@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

hedayat jafari

Street address

Imam Khomeini Square - Joibar Three Ways

City

Sari

Province

Mazandaran

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4815733971

Phone

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Email

hedayat2003@yahoo.com

Grant name

Grant code / Reference number

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

Yes

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

mohadese saberian

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Vesal street

City

Sari

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۴۸۱۶۷۱۵۷۹۳

Phone

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Hedayat jafari

Position

assistant profesor

Latest degree

Ph.D.

Other areas of specialty/work

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Email

Hedayat2003@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

mohadese saberian

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sari

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Phone

۳۳۳۶۷۳۴۲

Email

h_saberian@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Patient data - Demographic information and itching score at each stage in each group

When the data will become available and for how long

Data will be available after the study and statistical analysis.

To whom data/document is available

There is no limit.

Under which criteria data/document could be used

In order to conduct similar studies

From where data/document is obtainable

Dr.Hedayat jafari

What processes are involved for a request to access data/document

0

Comments