Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of aloe vera capsules on the rash of hemodialysis patients in Arak

Protocol summary

Study aim
Investigating the effect of aloe vera capsules on the rash of hemodialysis patients in Arak

Design
The present clinical trial study has a control group, with parallel groups, double-blind, randomized (using block randomization), phase 3 on 66 patients.

Settings and conduct
In this double-blind randomized clinical trial, hemodialysis patients suffering from pruritus referred to the dialysis department of Amir al-Momenin Hospital in Arak were divided into two identical intervention and control groups by means of block randomization. In the intervention group, patients received aloe vera capsules and in the control group, placebo capsules. In this study, the patients were blinded due to the identical appearance of the capsules, and the researcher was blinded due to not knowing the type of drug. Finally, two groups are compared in terms of itching intensity.

Participants/Inclusion and exclusion criteria
Conditions for inclusion in the study: Informed consent to enter the study; Age more than 18 years; There is no other reason for itching such as liver disease or allergy or skin disease; Ensuring the accuracy of dialysis patients; Patients diagnosed with chronic renal failure; Equal number of dialysis sessions per week. Conditions for not entering the study: History of itchy skin diseases; Taking pruritus drugs; Pregnancy or liver disorders; Hemodialysis for less than 6 months

Intervention groups
Intervention group: In addition to routine medications, the patient is given an aloe vera capsule containing 100 mg of aloe vera product every 12 hours in the first week and three times a week from the second week (after each hemodialysis). Control group: In addition to routine medications, the patient is given placebo capsules similar to aloe vera capsules containing starch according to the medication schedule of the intervention group.

Main outcome variables
intensity of pruritus

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191104045328N13**
Registration date: **2022-12-18, 1401/09/27**
Registration timing: **prospective**

Last update: **2022-12-18, 1401/09/27**
Update count: **0**

Registration date
2022-12-18, 1401/09/27

Registrant information

Name
Amin Haji seyyed hoseini

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3366 7583

Email address
amin.medstu@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-04-21, 1402/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the effect of aloe vera capsules on the rash of hemodialysis patients in Arak

Public title
The effect of aloe vera capsules on itching in hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Informed consent to enter the study Age more than 18 years There is no other reason for itching such as liver disease or allergy or skin disease. Ensuring the accuracy of dialysis patients Patients diagnosed with chronic renal failure Equal number of dialysis sessions per week

Exclusion criteria:
History of itchy skin diseases Taking pruritus drugs Pregnancy or liver disorders Hemodialysis for less than 6 months

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants will be assigned to two intervention and control groups based on the randomization sequence that will be generated in advance. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 8 blocks will be used to allocate the samples. In this way, using the site www.sealedenvelope.com, blocks of 8 letters A and B are randomly generated based on the sample size. The order of placement of letters A and B in each block from the first block to the last block is considered as a randomization sequence. The production of these blocks and their random sequence is completely done by this site and the researcher does not know how they are sequenced.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is of double-blind type. Blinding of the participants will be done using the same appearance of aloe vera capsules and placebo. Therefore, patients do not have any information about which group they will be assigned to. The blinding of the researcher is also done in this way that one person gives the drug to the patient, who has no knowledge of its type, and he himself completes the VAS scale for the patient.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Arak University of Medical Sciences

Street address
Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2022-06-13, 1401/03/23

Ethics committee reference number
IR.ARAKMU.REC.1401.145

Health conditions studied

1

Description of health condition studied
Pruritus

ICD-10 code
L29.8

ICD-10 code description
Other pruritus

Primary outcomes

1

Description
intensity of pruritus

Timepoint
Before and after the intervention

Method of measurement
Visual analogue scale of pruritus intensity

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to routine medicines, the patient is given aloe vera capsules containing 100 mg of aloe vera product twice a day (at 8 am and 8 pm) in the first week. From the second week, this capsule is given three times a week (after each hemodialysis, 1-2 hours apart from hemodialysis).

Category
Treatment - Drugs

2

Description
Control group: In addition to routine drugs, the patient is given placebo capsules similar to aloe vera capsules containing starch twice a day (at 8 am and 8 pm) in the first week. From the second week, this capsule is given three times a week (after each hemodialysis, 1-2 hours apart from hemodialysis).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Arak Amir Al Mo'menin Hospital

Full name of responsible person
Dr. Naser Saidi

Street address
Amir Al Mo'minin Hospital, Basij Square, Sardasht, Arak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Arak

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Grant name

Grant code / Reference number

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

Title of funding source
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Dr. Naser Saidi

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Nephrology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person

Dr. Seyed Amir Hossein Latifi

Position
Assistant Professor

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Person responsible for updating data

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resident

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long
Access will be from 2023/4/20 to 2026/4/20 for 3 years.

To whom data/document is available
University researchers

Under which criteria data/document could be used
Academic researchers or university professors or students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible persons in this study.

From where data/document is obtainable
Academic researchers and university professors, after contacting the respective professor by message or email, can request the utilization and use of data from Dr. Naser Saeedi and then Dr. Mustafa Taheri, respectively. Dr. Naser Saeedi: Phone: 09108072952; Email: nassersaidi@yahoo.com; Address: Amir Al Mo'minin Hospital, Basij Square, Sardasht, Arak. Dr. Mustafa Taheri: Phone: 09051036297; Email: dr.taheri110@gmail.com; Address: Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran.

What processes are involved for a request to access data/document
Letter writing should be done with professors and universities.

Comments