

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The effect of Aloe vera gel on pruritus severity of Hemodialysis patients

Protocol summary

Summary

The recent study aims to determine the effect of aloe vera gel to improving the quality of their lives of pruritus in hemodialysis patients. This study will be done in Valiasr Hospital of Arak with sample size of 64 people contains 32 people in intervention group and 32 people in control group. In this study, the researchers and data monitoring committee Will be blinded. The samples placed into two groups using table of random numbers: intervention group and control group. In this study, Clinical trial phase was not applicable. Inclusion criteria: a desire to participate in the study, at least 3 months of hemodialysis, continuous hemodialysis three times a week, a history of itching for at least 2 weeks, no disease causing itching (according to the doctor), a full awareness, lack of physical disability or a mental illness known as severe anxiety and depression, lack of using anti-itch drugs. Exclusion criteria: Patients who for any reason do not wish to continue participating in the study, if the patient uses anti itch medications during the intervention. In this study, 5-D Pruritus scale will be used. Intervention: For intervention group Aloe Vera gel will be used 2 times in a day for 1 month: 1) in day after hemodialysis 2) before night sleep. The severity of itch will be measured at the beginning of intervention and one month after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051411940N3**
Registration date: **2016-05-04, 1395/02/15**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-04, 1395/02/15

Registrant information

Name

Azam Malek Hoseini

Name of organization / entity

Arak University of Medical sciences

Country

Iran (Islamic Republic of)

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+98 86 1226 7892

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m.saeedi@arak.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Arak University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-02-09, 1394/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Aloe vera gel on pruritus severity of Hemodialysis patients

Public title

The effect of Aloe vera gel on pruritus severity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: a desire to participate in the study, at least 3 months of hemodialysis, continuous hemodialysis three times a week, a history of itching for at least 2 weeks, no disease causing itching (according to the doctor), a full awareness, lack of physical disability or a

mental illness known as severe anxiety and depression, lack of anti-itch drugs. Exclusion criteria: Patients who for any reason do not wish to continue participating in the study, if the patient uses anti itch medications during the intervention .

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 64

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The samples using table of random numbers placed in two groups intervention group and control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Valiasr Hospital, Alam al-Hoda Street, Emam khomeini St, Arak

City

Arak

Postal code

3848176941

Approval date

2013-10-28, 1392/08/06

Ethics committee reference number

92-157-6

Health conditions studied

1

Description of health condition studied

Chronic renal failure

ICD-10 code

N18.3

ICD-10 code description

Kidney damage with moderately decreased GFR (30-59 mL/min)

Primary outcomes

1

Description

The severity of itch

Timepoint

Initiation of intervention and one month after intervention

Method of measurement

(5-D Pruritus scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For intervention group Aloe vera gel will be used 2times in a day for 1 month: 1)First time in day after hemodialysis 2)Second time befor night sleep.

Category

Treatment - Drugs

2

Description

Control group: Control group will be receive routine cares and no specific drugs.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Azam Malek Hoseni

Street address

Valiasr Hospital,Arak

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Arak University of Medical Sciences

Full name of responsible person

Ms. Mir-Hosseini

Street address

Arak University of Medical Sciences, Alamolhoda
St,Arak

City

Arak

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 of Arak 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

Arak University of Medical Sciences

Full name of responsible person

Azam Malek Hoseini

Position

Educator

Other areas of specialty/work

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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