Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of topical effect of Aloe Vera gel and Violet oil with Hydroxyzine for pruritus and dry skin of hemodialysis patients

Protocol summary

Study aim
Comparison of topical effect of Aloe Vera gel and Violet oil with Hydroxyzine for pruritus and dry skin of hemodialysis patients

Design
Randomized One blinded Crossover clinical trial with control group on 45 patients

Settings and conduct
This is a Cross-Over study that will be performed on hemodialysis patients in dialysis centers in Birjand. The nephrologist, in collaboration with the researcher, will determine 45 eligible patients based on a checklist designed in accordance with the inclusion criteria and by convenient method. Antipruritic and anti-dryness medications will be discontinued 72 hours before the intervention. In the first stage, the first and second groups will be treated with Aloe Vera 94% of Si Gol company and Violet oil of Noshad company for 2 weeks and 2 times a day. The third group will use 10 mg Hydroxyzine tablets once a day (at night) for 2 weeks. The second and third stages will be done in cross form. To complete the questionnaire we utilize Assistant researcher who is blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Twenty years and older 2. The cause of dialysis is Chronic Renal Failure. 3. Patients undergoing hemodialysis for at least three months 4. Undergoing hemodialysis at least twice a week 5. History of pruritus for at least 4 weeks 6. The severity of Itching according to the VAS scale is ≥3. 7. The severity of Dry skin according to VAS scale is ≥3. 8. Informed consent Exclusion criteria: 1. Unwillingness to continue participation in the study 2. Severe side effects 3. Patient's Exclusion from the study

Intervention groups
Topical application of Aloe Vera gel and Violet oil in the intervention groups for two weeks and twice a day Taking 10 mg Hydroxyzine tablets in the control group for two weeks and once a day

Main outcome variables
Reduce itching and dry skin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200727048229N1**
Registration date: **2021-01-18, 1399/10/29**
Registration timing: **retrospective**

Last update: **2021-01-18, 1399/10/29**
Update count: **0**

Registration date
2021-01-18, 1399/10/29

Registrant information

Name
Nima Rezaalizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 13 4486 1278

Email address
nima.alizadeh@bums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-04, 1399/10/15

Expected recruitment end date
2021-01-14, 1399/10/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of topical effect of Aloe Vera gel and Violet oil with Hydroxyzine for pruritus and dry skin of hemodialysis patients

Public title
The Effect of Aloe Vera gel, Violet oil and Hydroxyzine on pruritus and dry skin of hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
20 Years and older The cause of dialysis is Chronic Renal Failure. Patients undergoing hemodialysis for at least three months Undergoing hemodialysis at least twice a week history of pruritus for at least 4 weeks The severity of Itching according to the VAS scale is ≥3. The severity of Dry skin according to VAS scale is ≥3. Do not use other treatments to relieve Itching and Dry skin during the study including Radiation Therapy, Acupuncture, Complementary Medicine, Topical treatments, Moisturizing. The patient does not attend another Clinical Trial within the next two months. The absence of Pruritic and non-Pruritic skin diseases such as Atopic Dermatitis, Chronic Liver and Biliary disease, HIV, Polycythemia, Skin Eczema, No Inflammatory Skin Lesions, the absence of known allergies (based on Expert doctor's opinion) The absence of Pregnancy and lactation Informed consent

Exclusion criteria:
Unwillingness to continue participation in the study for any reason Severe side effects like an allergic reaction to the Aloe Vera gel or Violet oil in patients during the intervention Patient leaving the dialysis center during the study period (due to death, emigration, kidney transplantation). Using other treatments to relieve pruritus during the study including Radiation Therapy, Acupuncture, Complementary Medicine, Topical Treatments Acute disease during the intervention Do not perform interventions for more than one week continuously. According to the researcher's diagnosis, the person is excluded from the study.

Age
From **20 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **45**
More than 1 sample in each individual
Number of samples in each individual: **3**
Because the research's method is crossover and there are three independent variables, so, each person will be intervened three times.

Randomization (investigator's opinion)
Randomized

Randomization description
All sample subjects are divided into three equal groups by simple randomized methods. first 45 cards (equal to the number of sample volumes) will be prepared. Then, one of the letters A, B or C will be written on each card (15 cards A, 15 cards B and 15 cards C). These cards will be placed inside a box. so, no one will be able to see the cards inside the box. After shuffling the cards by the researcher, patients are asked to randomly remove a card from the box (selected cards will not be returned to the box after selection). Thus, Participants are divided into three groups of 15 members A, B and C. Also, to determine the type of intervention for each group in each stage, another randomization will be done by the researcher. In this way, three cards are prepared and one of the numbers one, 2 and 3 will be written on each card. Numbers 1, 2 and 3 will belong to Aloe Vera gel, Violet oil and Hydroxyzine tablets, respectively. These cards will placed in a box and after shuffling, the researcher will randomly select a card for each group (the selected cards will not be returned to the box after selection). For example, the researcher for group A randomly selects a card from the box. This card contains the number one. So in the first stage, the intervention of group A will be the use of Aloe Vera gel. In the same way, this process will be repeated for the other two groups and the next steps.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the assistant researcher will complete the questionnaires to prevent bias in the results. Thus, the assistant researcher will be unaware of the groupings and the type of interventions performed in each group and by each Patient.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Moallem Blvd, Birjand university of medical sciences

City
Birjand

Province
South Khorasan

Postal code
9717953577

Approval date

2020-12-27, 1399/10/07

Ethics committee reference number

IR.BUMS.REC.1399.431

Health conditions studied

1

Description of health condition studied

Uremic Pruritus

ICD-10 code

L29

ICD-10 code description

Pruritus

2

Description of health condition studied

Uremic pruritus

ICD-10 code

L29

ICD-10 code description

Pruritus

3

Description of health condition studied

Skin dryness

ICD-10 code

L85.3

ICD-10 code description

Xerosis cutis

4

Description of health condition studied

Dialysis

ICD-10 code

Z49.1

ICD-10 code description

Dialysis (renal)

5

Description of health condition studied

Chronic kidney disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes

1

Description

Dimensions of Pruritus

Timepoint

The day before the intervention and the day after the intervention

Method of measurement

5-D itch scale

2

Description

Intensity of emotions with itching

Timepoint

The day before the intervention and the day after the intervention

Method of measurement

Researcher-made questionnaire (intensity of emotions with itching)

3

Description

The consequences of itching

Timepoint

The day before the intervention and the day after the intervention

Method of measurement

Researcher-made questionnaire (The consequences of itching)

4

Description

The severity of itching

Timepoint

The day before the intervention and the day after the intervention

Method of measurement

Visual Analogue Scale (VAS)

5

Description

The severity of dry skin

Timepoint

The day before the intervention and the day after the intervention

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

1

Description

Quality of life

Timepoint

at weeks 0 and 8

Method of measurement

Dermatology Life Quality Iindex (DLQI)

2

Description

Satisfaction rate of each intervention

Timepoint

The day after the end of each intervention

Method of measurement

Visual Analogue Scale (VAS)

Intervention groups

1

Description
In the first group, patients will be treated by 94% of SEAGULL's Aloe Vera gel twice per day for two weeks. Patients will use 3-5 cc of Aloe Vera gel to suit the dry and itchy area. After Wash out period the second treatment period will be continued by Violet oil made by Noshad Company twice per day for two weeks. Patients will use 3-5 cc of Violet oil to suit the dry and itchy area and after second Wash out period, the subjects will receive 10 mg Hydroxyzine tablets once a day (at night) for 2 weeks.

Category
Treatment - Drugs

2

Description
In the second group, patients will be treated by Violet oil made by Noshad Company twice per day for two weeks. Patients will use 3-5 cc of Violet oil to suit the dry and itchy area. After Wash out period, second treatment period will be continued by 10 mg Hydroxyzine tablets once a day (at night) for 2 weeks and after Wash out period, the subjects will receive 94% of SEAGULL's Aloe Vera gel twice per day for two weeks. Patients will use 3-5 cc of Aloe Vera gel to suit the dry and itchy area.

Category
Treatment - Drugs

3

Description
In the third group, patients will be treated by 10 mg Hydroxyzine tablets once a day (at night) for 2 weeks. After Wash out period, second treatment period will be continued by 94% of SEAGULL's Aloe Vera gel twice per day for two weeks. Patients will use 3-5 cc of Aloe Vera gel to suit the dry and itchy area and after Wash out period, the subjects will receive Violet oil made by Noshad Company twice per day for two weeks. Patients will use 3-5 cc of Violet oil to suit the dry and itchy area.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive center for the treatment of specific diseases

Full name of responsible person
Dr Anahita Arian

Street address
Beheshti Blvd, Comprehensive center for the treatment of specific diseases

City
Birjand

Province
South Khorasan

Postal code
9717953577

Phone
+98 13 4486 1278

Email
nimarezaalizadeh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Birjand University of Medical Sciences

Full name of responsible person
Dr. Ahmad Nasiri

Street address
Moallem Blvd, Birjand university of medical sciences

City
Birjand

Province
South Khorasan

Postal code
9717953577

Phone
+98 56 3238 1406

Email
nimarezaalizadeh@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Birjand 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
Birjand University of Medical Sciences

Full name of responsible person
Nima- RezaAliZadeh

Position
Master student of Medical-surgical Nursing

Latest degree
Bachelor

Other areas of specialty/work

Nursery
Street address
Moallem Blvd, Birjand university of medical sciences
City
Birjand
Province
South Khorasan
Postal code
9717953577
Phone
+98 13 4486 1278
Email
nimarezaaliazdeh@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Dr. Ahmad Nasiri
Position
Associate Professor of Nursing
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Moallem Blvd, Birjand university of medical sciences
City
Birjand
Province
South Khorasan
Postal code
9717953577
Phone
+98 56 3238 1406
Email
nimarezaalizadeh@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Nima- RezaAliZadeh
Position
Master student of Medical Surgical Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Moallem Blvd, Birjand university of medical sciences
City
Birjand
Province
South Khorasan
Postal code
9717953577
Phone
+98 13 4486 1278
Email
nimarezaalizadeh@gmail.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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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
The total potential data can be shared after unidentifiable people
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
Health Centers
From where data/document is obtainable
Faculty of Nursing and Midwifery of Birjand
What processes are involved for a request to access data/document
Immediately by visiting the Library of Birjand University Of Medical Science
Comments