Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Formulation and Evaluation of the Moisturizing Effect of Ammonium Lactate 12% Lotion on Dermatological Disease of the Uremic Patients

Protocol summary

Study aim

The aim of this study was to evaluate the effect of lotion produced in comparison with placebo lotion in reducing dry skin on the hands of patients undergoing peritoneal dialysis.

Design

Patients before treatment and one month later using a hand skin stereomicroscope with a magnification of 3 in terms of visual scoring of skin scale (VSS) which is evaluated to determine the amount of skin moisture and overall skin damage. Also, using the hand skin assessment form, the patient evaluates 4 variables including appearance, intactness moisture and itching or burning sensation by the patient with criteria (1-7) for each index.

Settings and conduct

Patients before treatment and one month later using a hand skin stereomicroscope with magnification*3 in terms of visual scoring of skin scale (VSS) which is evaluated to determine the amount of skin moisture and overall skin damage.

Participants/Inclusion and exclusion criteria

Entry conditions: presence of dry skin in dialysis patients
Conditions of non-entry: no itching on the skin of the dialysis patient and unwillingness to participate in the trial

Intervention groups

Uric patients treated with peritoneal dialysis who have dry skin are randomly divided into two groups: 1- lotion and 2- placebo (lotion without ammonium lactate) The results before and after the intervention are evaluated in case and control groups.

Main outcome variables

The system has 6 degrees that are rated by the researcher from the number of normal skin without skin and skin irritation to degree 0 of skin cracks and extensive red fissures or occasional bleeding.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171009036672N2**
Registration date: **2022-12-24, 1401/10/03**
Registration timing: **retrospective**

Last update: **2022-12-24, 1401/10/03**
Update count: **0**

Registration date

2022-12-24, 1401/10/03

Registrant information

Name
omid rajabi

Name of organization / entity
university of medical sciences

Country
Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-20, 1400/12/29

Expected recruitment end date

2022-04-18, 1401/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Formulation and Evaluation of the Moisturizing Effect of Ammonium Lactate 12% Lotion on Dermatological Disease of the Uremic Patients

Public title

Moisturizing effect of 12% ammonium lactate lotion in the treatment of dry skin in dialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Uric patient treated with peritoneal dialysis Existence of dry skin

Exclusion criteria:

History of sensitivity to any of the components of the product Reluctance to participate or continue the plan Existence of skin diseases except dryness

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

A double-blind randomized comparative clinical trial was conducted to investigate the effectiveness of ammonium lactate 12% against placebo lotion without medicinal substance. A study in the form of a questionnaire design related to the complications of uremic itching and the effect of 12% ammonium lactate lotion, which was provided to the participants and was filled again four weeks later by them to compare the effect of the lotion. The randomization method was done in a simple way and randomly in two groups. The randomization unit was checked individually in two different groups. The randomization tool was filled in the form of a hand skin evaluation questionnaire (expression of uremic itching side effects) before and after using the drug and for four weeks. Finally, using statistical software, the percentage of patients' satisfaction with the drug was evaluated. The way of constructing the random sequence was that the patients were randomly selected in two different groups Concealment was done in such a way that the patients did not know about the use of drugs or placebos, and drug distribution was done by the researcher . In this way, the first group used the drug (ammonium lactate 12%) and the second group used a placebo, i.e. a 50% w/w paraffin emulsion in water.

Blinding (investigator's opinion)

Double blinded

Blinding description

The method of blinding was done in such a way that the participants, the ward nurse and the clinical supervisor were not aware of the drug or placebo, and the drug distribution was done by the researcher. Also, the person evaluating the outcome and the person analyzing the data did not know how to distribute the drug and placebo among the patients. In this way, the first group of participants used the drug (ammonium lactate 12%) in one day without knowing the name, and the second group used a placebo, i.e. 50% w/w paraffin emulsion in water. Patients were randomly selected according to uremic pruritus problems: the first group used medicine and the second group used placebo In this double-blind study, patients in both groups are evaluated before treatment and one month after using a hand skin stereomicroscope with 3x magnification in terms of visual scoring to determine the level of skin moisture and overall skin damage. This system has 6 grades, from 6 (normal skin without crusting and skin irritation) to 0 (skin cracks and wide fissures, redness or occasional bleeding) by the researcher and the ward nurse.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Mashhad university of Medical Sciences Research

Street address

Research and Technology Vice-Chancellor, next to Hoize Cinema, Qurashi Building, Mashhad, University St.

City

mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2019-05-19, 1398/02/29

Ethics committee reference number

IR.MUMS.PHARMACY.REC.1398.027

Health conditions studied

1

Description of health condition studied

Severe dry skin

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Determining skin moisture
Timepoint
Before starting treatment and 3 days after taking the drug for a month
Method of measurement
The system has 6 degrees, from a score of 6 normal skin without scales to 0 degrees skin cracks

2

Description
General skin damage
Timepoint
Before starting treatment and 3 days after taking the drug for a month
Method of measurement
The system has 6 degrees, from a score of 6 normal skin without scales to 0 degrees extensive fissures redness or occasional bleeding

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The effectiveness of ammonium lactate 12% was investigated. A study in the form of a questionnaire design related to the complications of uremic itching and the effect of the drug, which was given to the participants and filled again four weeks later by them to compare the effect of the lotion.
Category
Treatment - Drugs

2

Description
control group: Placebo, lotion, placebo without medicinal substance, a study in the form of a questionnaire design related to the effects of uremic itching and the effect of the placebo, which was given to the participants and filled again four weeks later by them to compare the effect of the lotion.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital of Mashhad
Full name of responsible person
omid rajabi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice President of Research and Technology Mashhad University of Medical Sciences
Full name of responsible person
majid ghayour mobarhan
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Research and Technology Vice-Chancellor, next to Hoize Cinema, Qurashi Building, Mashhad, University St.
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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
Vice President of Research and Technology Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
atoosa haghighizadeh

Position
postdoc

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Ph.D.

Other areas of specialty/work
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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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
How to improve patients can be presented in the form of a table

When the data will become available and for how long
Access period starts from the summer of 1401 for 6 months

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Available for medical purposes and through a doctor

From where data/document is obtainable
emails

What processes are involved for a request to access data/document
The data will be emailed to them within a week

Comments