

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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)

Phone

+98 51 3884 3483

Email address

rajabio@mums.ac.ir

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

Street address

faculty of pharmacy, ferdowsi university of mashhad, park sq.,montazeri blv.

City

mashhad

Province

Razavi Khorasan

Postal code

9188617871

Phone

+98 51 3180 1126

Fax

+98 51 3884 3483

Email

rajabio@mums.ac.ir

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

Street address

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

City

mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Fax

+98 51 3843 0249

Email

vcresraech@mums.ac.ir

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

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

atoosa haghhighizadeh

Position

postdoc

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

pharmacy school, ferdowsi university of mashhad,
park sq., montazer blv.

City

mashhad

Province

Razavi Khorasan

Postal code

9188617871

Phone

+98 51 3180 1126

Fax

+98 51 3884 3483

Email

atoosa.hz@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

omid rajabi

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

pharmacy school, ferdowsi university of mashhad,
park sq., montazeri blv.

City

mashhad

Province

Razavi Khorasan

Postal code

9188617871

Phone

+98 51 3180 1126

Fax

+98 51 3884 3483

Email

rajabio@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

yohana seyed hosseini

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

pharmacy school, ferdowsi university of mashhad,
park sq., montazeri blv.

City

mashhad

Province

Razavi Khorasan

Postal code

9177948954

Phone

+98 51 3180 1126

Email

yohanna.hosseini73@gmail.com

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