Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison effect of Olopatadine %0.2 cream with Fluocinolone %0.025 cream in the treatment of hand eczema in patients

Protocol summary

Study aim

Investigating the effect of Olopatadine 0.2% cream compared to Fluocinolone 0.025 % cream in the treatment of hand eczema in patients referred to the skin clinic of imam Khomeini Hospital, Ahvaz

Design

The clinical trial has 2 groups with randomized double-blind parallel groups, phase 2 on 76 patient ,random numbers table was used for randomization

Settings and conduct

This study will be conducted in the field of hand eczema treatment of patients referred to the skin clinic of Imam Hospital .In this way ,the people eligible to enter the study will be randomly divided into two groups and one group will be given olopatadine cream .Both of them are unaware of the contents of each of the creams, the method of use is fully explained to the patient ,and by using the HESCI score for the clinical symptoms of eczema and the NRS score for the itch of the patient ,the rate of improvement of the patient's symptoms every two weeks and at the end it is evaluated after one month from the end of the treatment

Participants/Inclusion and exclusion criteria

All patients over 18 years old whose hand eczema is confirmed by biopsy or dermatologist diagnosis has been

Intervention groups

In this study, patients with hand eczema were divided into two groups, one group was treated with olopatadine cream and the other group was treated with fluocinolone cream. Both creams are in the form of 1 gram twice a day

Main outcome variables

Reducing the use of topical corticosteroids due to its many side effects in long-term use, restoring skin barrier function by topical antihistamines (in this study, olopatadine cream) reducing the need for oral antihistamines

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240614062122N1**
Registration date: **2024-06-29, 1403/04/09**
Registration timing: **prospective**

Last update: **2024-06-29, 1403/04/09**
Update count: **0**

Registration date

2024-06-29, 1403/04/09

Registrant information

Name

Zahra Joriz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 3609

Email address

mina.joriz@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-06, 1403/04/16

Expected recruitment end date

2024-10-07, 1403/07/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of Olopatadine %0.2 cream with Fluocinolone %0.025 cream in the treatment of hand eczema in patients

Public title
Effect of Olopatadine in treatment of hand eczema
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with a diagnosis of hand eczema ,(including all types of eczema in the acute phase)whose disease is confirmed by biopsy or a dermatologist's diagnosis The age of the patients is 18 years or older Consent to participate in the study
Exclusion criteria:
Pregnant and breastfeeding Systemic treatment has been done in the last 3 months or local treatment 2 weeks ago The place of use of the medicine is infectious
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the allocation of patients to each of the treatment groups will be done by random method (the patients are divided into two groups A and B using the coin toss method and then using the table random numbers are assigned to each group
Blinding (investigator's opinion)
Double blinded
Blinding description
Both categories of drugs are in tubs with the same shape,indistinguishable for the patient and the researcher,and with the numbering that will be written on them by the Faculty of Pharmacy when both drugs are tubed.It will be provided to the patient and the researcher also has the role of clinical caregiver and outcome assessor and date analyst,so the researcher and the patient are kept blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jondishapur University of Medical Sciences
Street address
No.143,Taef Apartment, West Dez Street ,Amaniyeh
City
Ahvaz
Province
Khouzestan
Postal code
6133864473
Approval date
2024-06-05, 1403/03/16
Ethics committee reference number
IR.AJUMS.REC.1403.111

Health conditions studied

1

Description of health condition studied
Investigating the effect of Olopatadine cream on hand eczema
ICD-10 code
L20.8
ICD-10 code description
Other atopic dermatitis

Primary outcomes

1

Description
The severity score of the clinical symptoms of hand eczema using the Hand Eczema Severity Index ,as well as the evaluation of the severity of itching using the Neurologic Rating Scale
Timepoint
Measuring the intensity of the clinical symptoms of hand eczema using the Hand Eczema Severity Index and itching intensity using the Neurologic Rating Scale at the beginning of the study ,then every two weeks until the end of the study (for 3 months) and 4 weeks after the end of the study
Method of measurement
Hand Eczema Severity Index Neurologic Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 38 patients with hand eczema was

treated with 0.2% Olopatadine cream ,and each patient applied 1 gram or one centimeter of the cream on the finger twice a day and rotated it on massage the eczema lesion. Olopatadine drug ,which was originally available in power form, was formulated by the Faculty of Pharmacy of Jundishapur University of Ahvaz in accordance with the American Pharmacopoeia and the principles of pharmaceutics and will be provided to the patient as a 0.2% cream in multi-layer laminated tubes with a label attached.

Category

Treatment - Drugs

2

Description

Intervention group: 38 patients with hand eczema was treated with Fluocinolone 0.025% cream ,and each patient applied 1 gram or one centimeter of the cream on the finger twice a day and rotated it on massage the eczema lesion. Fluocinolone cream is produced by Tehran Chemie Pharmaceutical Company ,and it is provided to the patients as a cream in multi-layer laminated tube similar to the cover of Olopatadine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dermatology Clinic of Imam Khomeini Hospital,Ahvaz
Full name of responsible person
Pazyar Nader
Street address
No.143,Taef Apartment, West Dez Street ,Amaniyeh
City
Ahvaz
Province
Khouzestan
Postal code
6133864473
Phone
+98 61 3333 3609
Email
Dr.pazyar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Pazyar Nader
Street address
No.143,Taef Apartment, West Dez Street ,Amaniyeh
City
Ahvaz
Province
Khouzestan
Postal code
6133864473
Phone
+98 61 3333 3609
Email
Dr.pazyar@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Pazyar Nader
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
No.143,Taef Apartment, West Dez Street ,Amaniyeh
City
Ahvaz
Province
Khouzestan
Postal code
6133864473
Phone
+98 61 3333 3609
Email
Dr.pazyar@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Pazyar Nader
Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

No.143,Taef Apartment, West Dez Street ,Amaniyeh

City

Ahvaz

Province

Khouzestan

Postal code

6133864473

Phone

+98 61 3333 3609

Email

Dr.pazyar@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Pazyar Nader

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

No.143,Taef Apartment, West Dez Street ,Amaniyeh

City

Ahvaz

Province

Khouzestan

Postal code

6133864473

Phone

+98 61 3333 3609

Email

Dr.pazyar@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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