Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Evaluating the efficacy of corticosteroid free ointment in the treatment of patient with eczema

Protocol summary

Study aim
The main goal of this project is to investigate the effect of corticosteroid-free ointment (containing suaeda seed oil containing 77% omega-6 + biotin, pyridoxamine phosphate + cobalamin B12 + vitamin E + zinc oxide and calamine powder) On mild to moderate eczema skin disorders as well as evaluation of possible side effects of this product.

Design
Double blinded randomized (block randomization) phase 3 clinical trial with control group

Settings and conduct
Based on the results of the animal phase and human case studies, treatment duration of 21 days and 3 times per day is suggested. Also to check for side effects of this product, again check for symptoms of anti-eczema effects, for example, whether there is more inflammation, itching, redness and burning. Finally, the data were analyzed by SPSS software using ANOVA test. In this study, the outcome assessor and participants have been blinded. The outcome assessor is people who are responsible for gathering data and outcome variables and does not know which participant received which drug.

Participants/Inclusion and exclusion criteria
Only patients with active eczema lesion are included in this study.

Intervention groups
Three treatment groups are used to implement this scheme. By the way, the ointments given to people are similar in shape and color, 1) A group formulated with ointment containing active ingredients, 2) A group of ointments used without active ingredients and 3) A group that uses standard ointments such as eucerin. In this study, 25 individuals were used in each group using statistical calculations.

Main outcome variables
1) no itching, 2) no redness, 3) no burning, 4) less inflammation, and 5) wound healing.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140624018210N10**
Registration date: **2020-12-13, 1399/09/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-13, 1399/09/23**
Update count: **0**

Registration date
2020-12-13, 1399/09/23

Registrant information

Name
Elham Behrangi

Name of organization / entity
Iran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-01, 1399/09/11

Expected recruitment end date
2021-03-01, 1399/12/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the efficacy of corticosteroid free ointment in the treatment of patient with eczema

Public title
Formulation and manufacturing of corticosteroid free ointment for treatment of eczema

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Only patients with active eczema lesions are included in this study.

Exclusion criteria:
Patients with very large (severe) lesions Patients with a history of skin diseases other than eczema

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization is a commonly used technique in clinical trial design to reduce bias and achieve balance in the allocation of participants to treatment arms. This method increases the probability that each arm will contain an equal number of individuals by sequencing participant assignments by block.The randomization unit is individual and randomization's tool is a statistical software.randomization is a simple method using statistical software SPSS version 22.Both drugs are packaged in the same container of 100 grams. The randomization list is prepared by a statistical consultant and a number is given to each medicine container. The participant and the main researcher and the doctor who is responsible for following up the patient and evaluating the outcome of the drug use are not aware of the nature of the drug used.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the outcome assessor and participants have been blinded. The outcome assessor is people who are responsible for gathering data and outcome variables and does not know which participant received which drug.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Iran University Of Medical sience

Street address
Iran university -Hemat Highway

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Tehran

Province
Tehran

Postal code
19922347512

Approval date
2020-11-30, 1399/09/10

Ethics committee reference number
IR.IUMS.REC.1399.946

Health conditions studied

1

Description of health condition studied
eczema

ICD-10 code
L20.89

ICD-10 code description
Other atopic dermatitis

Primary outcomes

1

Description
1) itching 2) redness 3) burning 4) inflammation 5) wound healing

Timepoint
End of the treatment period

Method of measurement
Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A group treated with formulated ointment containing active ingredients .
Formulation:1)First, dissolve 8 grams of carbomer in one and a half liters of water and then bring the dissolved carbomer to a temperature of 70 degrees Celsius.2)In the next step, sterile acetyl alcohol + acetyl alcohol +

liquid paraffin + GMS 32 g + stearate 20, + dimethicone + Vaseline is added and placed on the heater to dissolve completely.3)The active ingredients are weighed on the scales and added to the container, respectively. The active ingredients: omega 6 (linoleic acid) + zinc oxide + biotin + vitamin B6 + vitamin B12 + menthol were added one gram. It should be noted that the active ingredients are micronized4)Then items 1 and 2 were mixed together and homogenized with a homogenizer and finally triethanolamine was added.5)Methyl isothiosolonium preservative was added for 400C. all patients have signatured informed consent documents and were given a complete explanation about the sudy procedures .after the first visit and examination, patients would start the treatment period and after a month of treatment would be re-examined for treatment efficacy and followup checkups. treatment dosage is variable from 2 to 10 gr and should be administred on the lesion two times per day. oinment administration procedure is dependent on lesion size and each patient should use the oinment based on their lesion size in a manner that the surface of lesion shoud be fully covered with the oinment. The place of cream formulation has been done in Oud Kala factory (Alborz province, Baharestan town, Golestan 10th, Oud Kala factory (health-pharmaceutical products factory))

Category
Treatment - Drugs

2

Description
Intervention group: A group that uses standard ointments such as eucerin

Category
Treatment - Drugs

3

Description
Control group: A group treated with ointments without active ingredients

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasool-E-Akram Hospital

Full name of responsible person
Dr Elham Behrangi

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Satarkhan st , Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Iran 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
Islamic Azad University

Full name of responsible person
Dr. Nuredin Bakhtiari

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Biochemistry

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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No - There is not a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Findings of the study, demographic data of participants in the study, in addition to descriptive and analytical analysis of variables
When the data will become available and for how long
Availability 6 months after the end of study
To whom data/document is available
no limitation
Under which criteria data/document could be used
In the case of comparison with other similar trials or treatment
From where data/document is obtainable
Iran University of Medical Sciences
What processes are involved for a request to access data/document
By referring to the central library of Iran University of Medical Sciences can access to the text of the final report or article.
Comments