Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of therapeutic effect of topical GAMMANOL cream- contains 6% gamma linolenic acid- with mometasone 0/1% cream in hand eczema by two scoring systems of DLQI and HECSI in patients with chronic or subacute hand eczema

Protocol summary

Study aim
Comparison the therapeutic effect of Gammanol cream containing 6% gammalinolenic acid with mometasone cream in hand eczema

Design
Clinical trial with control group, two arm parallel group, double blinded, randomized, phase 3 on 52 patients. Randomization was based on the permutation block method with four block.

Settings and conduct
Patients with chronic or subacute hand eczema receive a number, according to the referral time. Two kinds of drugs consist of Gammanol cream and mometasone cream are packed in the bottles with the same shape and weight and are randomized based on the permutation block method. Every patient is given the drug with the same number. The patients, the main investigator physician and the physician who is responsible for follow up have no information about kind of the drug. Two indexes of DLQI and HECSI are measured in the first visit and after 1 month of regular drug use and the changes are evaluated.

Participants/Inclusion and exclusion criteria
Inclusion criteria: chronic or subacute hand eczema, unilateral or bilateral. Exclusion criteria: pregnancy or lactation.

Intervention groups
Patients with chronic or subacute hand eczema are divided in two groups of 26 patients, to use Gammanol cream or mometasone cream. Both drugs are packed in bottles with the same shape and each one weighs 30gr. Patients are given a number based on the referral time and also , each drug has a number based on the randomization list and each patients is given the drug with the same number.

Main outcome variables
Hand eczema severity score; dermatologic life quality index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201101049215N1**
Registration date: **2020-11-22, 1399/09/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-22, 1399/09/02**
Update count: **0**

Registration date
2020-11-22, 1399/09/02

Registrant information

Name
Farideh Jokar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3212 5239

Email address
nedazakeri@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-22, 1398/09/01

Expected recruitment end date
2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effect of topical GAMMANOL cream- contains 6% gamma linolenic acid- with mometasone 0/1% cream in hand eczema by two scoring systems of DLQI and HECSI in patients with chronic or subacute hand eczema

Public title

Effect of Gammalinolenic acid in hand eczema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic or subacute hand eczema, unilateral or bilateral

Exclusion criteria:

Acute hand eczema pregnant or lactating women Use systemic immunosuppressant drug for one recent month Use topical therapies for hand eczema for two recent weeks To have localized infection in hands

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is based on the permutation block method with four blocks in each group, randomization list was prepared for this purpose.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drugs in this trial are Mometasone 0.1% cream and Gammanol cream containing 6% gammalinolenic acid; both drugs are packed in bottles with the same shape and each one weighs 30 gr. Statistic advisor prepares a randomization list and each bottle is given a number. The participant, the main investigator, and the physician who is responsible for follow up and evaluating the outcome of drug use, have no information about the kind of drug.

Placebo

Not used

Assignment

Parallel

Other design features

In this study we compare the therapeutic effect of gammalinolenic acid with mometasone which is the main and common therapy for hand eczema.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Ethics committee of Shiraz University of Medical Sciences, University of Medical Sciences Building, Karimkhan Zand Ave., Shiraz

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Province

Fars

Postal code

7185996187

Approval date

2019-10-09, 1398/07/17

Ethics committee reference number

IR.SUMS.MED.REC.1398.431

Health conditions studied

1

Description of health condition studied

Hand eczema

ICD-10 code

XII

ICD-10 code description

Disease of the skin and subcutaneous tissue

Primary outcomes

1

Description

Han Eczema Severity Score and Dermatology Life Quality Score

Timepoint

First visit and after one month of drug use

Method of measurement

measurement table of hand eczema severity index and questionnaire of dermatologiy life quality index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 26 patients with chronic and subacute hand eczema who receive Gammanol cream containing 6% gammalinolenic acid, manufactured by Asacpharma company, at the rate of 30 grams. Patients must use this cream for one month, the dosage is explained to the patients during a ten minute session by Finger Tip Unit. Finger Tip Unit of a cream is equivalent to 0.5 gram for each hand and finally 30 gram is used during one month for both hands.

Category
Treatment - Drugs

2

Description
Control group: 26 patients with chronic and subacute hand eczema who receive the standard and usual therapy which is mometasone 0.1% cream, at the rate of 30 grams. Patients must use this cream for one month, the dosage is explained to the patients during a ten minute session by Finger Tip Unit. Finger Tip Unit of a cream is equivalent to 0.5 gram for each hand and finally 30 gram is used during one month for both hands.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Faghihi hospital

Full name of responsible person
Farideh Jokar

Street address
Dermatology clinic, Shahid Faghihi hospital, Karimkhan Zand Ave., Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
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Grant name
University

Grant code / Reference number
97-01-01-17945

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

Title of funding source
Shiraz 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

2

Sponsor

Name of organization / entity
Research Deputy of Shiraz University of Medical Sciences

Full name of responsible person
Abbas Rezaeeyan Zadeh

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Web page address

Grant name
university

Grant code / Reference number

97-01-01-17945

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

Yes

Title of funding source

Research Deputy of Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Farideh Jokar

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Farideh Jokar

Position

professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Marjan Baniahmad

Position

Resident

Latest degree

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Participants personal data, All the data is potentially

available after making the people unrecognizable

When the data will become available and for how long

Start access 6 months after print result

To whom data/document is available

researchers employed in academic and scientific institutions

Under which criteria data/document could be used

Research use of the data of this study is allowed communication in the manner of e-mail

From where data/document is obtainable

web page of Shiraz University of Medical Sciences, Research unit Shahid Faghihi hospital, dermatology clinic, department office E-mail nedazakeri@yahoo.com

What processes are involved for a request to access data/document

After reviewing their written request, the data is given to them as soon as possible

Comments