

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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

Hand eczema severity score; dermatologic life quality index

#### 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

#### 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

##### City

Shiraz

##### 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 dermatology 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

#### City

Shiraz

#### Province

Fars

#### Postal code

7134846114

#### Phone

+98 71 3231 9049

#### Fax

#### Email

nedazakeri@yahoo.com

#### Web page address

<http://faghihi.sums.ac.ir>

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Shiraz University of Medical Sciences

### Full name of responsible person

Abbas Rezaeeyan Zadehch

### Street address

Research Deputy Unit, Shiraz university of Medical Sciences, Karimkhan Zand Ave., Shiraz

### City

Shiraz

### Province

Fars

### Postal code

71348-14336

### Phone

+98 71 3230 5410

### Email

[vcrdep@sums.ac.ir](mailto:vcrdep@sums.ac.ir)

### Web page address

<http://sums.ac.ir>

### 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

#### Street address

Research Deputy Unit, Shiraz university of Medical Sciences, Karimkhan Zand Ave., Shiraz

#### City

Shiraz

#### Province

Fars

#### Postal code

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#### Phone

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#### Email

[vcrdep@sums.ac.ir](mailto:vcrdep@sums.ac.ir)

#### 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

**Street address**

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

**City**

Shiraz

**Province**

Fars

**Postal code**

7134846114

**Phone**

+98 71 3212 5239

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nedazakeri@yahoo.com

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**Person responsible for scientific 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

**Street address**

Dermatology clinic, Shahid Faghihi hospital,  
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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Marjan Baniahmad

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

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

**City**

Shiraz

**Province**

Fars

**Postal code**

7134846114

**Phone**

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**Email**

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**Web page address**

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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**