

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the efficacy of ivermectin 1% cream and ketoconazole 2% cream in treatment of facial seborrheic dermatitis

#### Protocol summary

##### Study aim

Comparison of the efficacy of ivermectin 1% cream and ketoconazole 2% cream in the treatment of facial seborrheic dermatitis

##### Design

Phase 3, parallel group, clinical trial, with consecutive sampling, including 40 patients, double blinded, computerized randomized with permuted blocks

##### Settings and conduct

The study is conducted in the dermatology clinic of Shiraz University of Medical Sciences. Group 1 will apply ivermectin 1% cream once overnight and cold cream twice daily on the face. Group two will apply ketoconazole 2% cream twice daily and cold cream once overnight on face. The patients are assessed at the beginning of treatment, first month and 2nd month by dermacatch and camera photography. The patients and outcome assessor are blinded to the type of treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Older than 18 years of age patients with severe facial seborrheic dermatitis  
Exclusion criteria: Using antibiotics or immunomodulatory drugs since one month before beginning of the research  
Using any topical drugs that can affect seborrheic dermatitis since two weeks before beginning of the research  
Using any oral drugs that can affect seborrheic dermatitis since one month before beginning of the research  
Human immunodeficiency virus infection  
Parkinson's disease  
Pregnancy  
Lactation  
sensitivity to the research drugs

##### Intervention groups

Intervention group: Ivermectin 2% cream (Ajanta, Gujrat, India) is applied once overnight and cold cream twice daily on the face. Control group: Ketoconazole 2% cream (Najo, Tehran, Iran) is applied twice daily and cold cream once overnight on the face.

##### Main outcome variables

Determination of seborrheic dermatitis area severity index (SEDASI) score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210222050452N1**

Registration date: **2021-07-15, 1400/04/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-07-15, 1400/04/24**

Update count: **0**

##### Registration date

2021-07-15, 1400/04/24

##### Registrant information

##### Name

Fatemeh Shamshiri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3226 0739

##### Email address

fatemeh.shamshiri@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-21, 1400/02/31

##### Expected recruitment end date

2022-05-21, 1401/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the efficacy of ivermectin 1% cream and ketoconazole 2% cream in treatment of facial seborrheic dermatitis

#### Public title

Comparison of the efficacy of ivermectin cream and ketoconazole cream in treatment of facial seborrheic dermatitis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients more than 18 years old Clinical diagnosis of seborrheic dermatitis (erythematous plaques with greasy and yellowish scales on nose, nasolabial fold, forehead, frown lines, cheek and chin)

##### Exclusion criteria:

Severe facial seborrheic dermatitis Using antibiotics or immunomodulatory drugs since one month before beginning of the research Using any topical drugs that can affect seborrheic dermatitis since two weeks before beginning of the study Using any oral drugs that can affect seborrheic dermatitis since one month before beginning of the research Human immunodeficiency virus infection Pregnancy Sensitivity to the research drugs constituents Parkinson's disease Lactation

#### Age

From **18 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Outcome assessor

#### Sample size

Target sample size: **40**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomization is performed by random allocation software and participants are randomly allocated in the intervention or control group. Randomization of 40 participants in the software is performed by randomization blocks size 4 with random ratio of 1:1. The output of the software is a table that shows the number of each participant is allocated in the intervention or control group. The medications are in the similar tubes labeled by numbers of the patients.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The problem of discrepancy of numbers of daily application of the two under investigation-creams (ketoconazole cream twice daily and ivermectin cream once overnight), was solved by adding cold cream (non-effective on seborrheic dermatitis), once overnight in ketoconazole group and twice daily in ivermectin group. All drugs are packed in similar containers and have similar color, smell, and texture; and, the containers allocated to each patient are labelled with the same

patients of patient recruitment number. Care provider and investigator that deliver the creams are not involved in the outcome assessment. The outcome assessor is not aware of the type of drugs in each patient. Due to similarity of the drugs and the instructions, the patients are also unaware of the type of used drugs. Therefore the research will be double-blinded.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

Shiraz University of Medical Science, zand Ave.

##### City

Shiraz

##### Province

Fars

##### Postal code

71348-14336

#### Approval date

2021-02-14, 1399/11/26

#### Ethics committee reference number

IR.SUMS.MED.REC.1399.595

## Health conditions studied

### 1

#### Description of health condition studied

Facial seborrheic dermatitis

#### ICD-10 code

L21.9

#### ICD-10 code description

Seborrheic dermatitis, unspecified

## Primary outcomes

### 1

#### Description

Determination of seborrheic dermatitis area and severity index (SEDASI) score

#### Timepoint

Before intervention and 1 and 2 months after starting intervention

#### Method of measurement

seborrheic dermatitis area and severity index (SEDASI) score formula

## Secondary outcomes

### 1

#### Description

Skin erythema index

#### Timepoint

before intervention and 1 and 2 months after starting intervention

#### Method of measurement

Dermacatch instrument

### 2

#### Description

Pruritus severity

#### Timepoint

before intervention and 1 and 2 months after starting intervention

#### Method of measurement

ItchyQuant itch illustrated numerical rating scale

### 3

#### Description

Quality of life

#### Timepoint

before intervention and 2 months after starting intervention

#### Method of measurement

Dermatology Life Quality index questionnaire Persian version

## Intervention groups

### 1

#### Description

Intervention group: Ivermectin 2% cream (Ajanta, Gujrat, India) is applied once overnight and cold cream twice daily on the face.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Ketoconazole 2% cream (Najo, Tehran, Iran) is applied twice daily and cold cream once overnight on the face.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dermatology clinic, Shahid Faghihi hospital

##### Full name of responsible person

Mozhdeh Sepaskhak

#### Street address

Dermatology clinic, Faghihi hospital, Zand St.

#### City

Shiraz

#### Province

Fars

#### Postal code

7134844119

#### Phone

+98 71 3235 1087

#### Email

sepaskhah@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Abbas Rezaeian zade

##### Street address

Research Council, Shiraz University of Medical Sciences, Zand St

##### City

Shiraz

##### Province

Fars

##### Postal code

7134814336

##### Phone

+98 71 3235 7282

##### Email

vrdep@sums.ac.ir

#### Grant name

Research grant of the Research Council of Shiraz University of Medical Sciences

#### Grant code / Reference number

22355

#### 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

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

**Full name of responsible person**

Mozhdeh Sepaskhah

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Dermatology

**Street address**

Dermatology clinic, Faghihi hospital, Zand St.

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**Province**

Fars

**Postal code**

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+98 71 3484 6316

**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mozhdeh Sepaskhah

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Dermatology

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**City**

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**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Fatemeh Shamshiri

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

No. 14, 7th alley, Hor street

**City**

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**Province**

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**Postal code**

7133973333

**Phone**

+98 71 3226 0739

**Fax****Email**

fatemeh.shamshiri@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