

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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)

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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.

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7134844119

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaeian zade

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Research Council, Shiraz University of Medical Sciences, Zand St

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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

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

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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

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Resident

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Medical doctor

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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