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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+98 71 3226 0739

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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:

Ṡevere 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'sdisease 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 MedicalSscience, 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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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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Position
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Latest degree
Subspecialist
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Person responsible for updating data

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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