

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of rosemary extract lotion in the treatment of dandruff in seborrheic dermatitis in comparison with ketoconazole %2 lotion a double-blind clinical trial

Protocol summary

Study aim

Comparison of the efficacy of rosemary lotion and ketoconazole 2% lotion in the treatment of scalp seborrheic dermatitis

Design

Phase 3, parallel group, clinical trial, with consecutive sampling, including 42 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 rosemary lotion twice daily on the scalp. Group two will apply ketoconazole 2% lotion twice daily on the scalp. The patients are assessed at the beginning of treatment, first month and 2nd month. The patients and outcome assessor are blinded to the type of treatment.

Participants/Inclusion and exclusion criteria

Patients 18-60 years old clinical diagnosis of scalp seborrheic dermatitis; ASFS score > 10; DLQI index > 2

Intervention groups

Intervention group: Rosemary lotion is applied twice daily on the scalp. Control group: Ketoconazole 2% lotion is applied twice daily on the scalp.

Main outcome variables

Adherent scalp flaking score (ASFS score)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221001056063N1**

Registration date: **2022-10-11, 1401/07/19**

Registration timing: **prospective**

Last update: **2022-10-11, 1401/07/19**

Update count: **0**

Registration date

2022-10-11, 1401/07/19

Registrant information

Name

Fatemeh Alesana

Name of organization / entity

Country

Iran (Islamic Republic of)

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dermatologist2019@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of rosemary extract lotion in the treatment of dandruff in seborrheic dermatitis in comparison with ketoconazole %2 lotion a double-blind clinical trial

Public title

Comparison of the efficacy of rosemary lotion and ketoconazole lotion in treatment of seborrheic dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 18-60 years old clinical diagnosis of scalp seborrheic dermatitis ASFS score > 10 DLQI index > 2

Exclusion criteria:

Severe seborrheic dermatitis in other areas 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 Other scalp diseases Scalp surgery in the previous month Sensitivity to the research drugs Pregnancy Lactation

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **42**

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 42 participants in the software is performed by randomization blocks 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

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

Not 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 Sciences, Zand Ave.

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2022-05-22, 1401/03/01

Ethics committee reference number

IR.SUMS.MED.REC.1401.090

Health conditions studied**1****Description of health condition studied**

Scalp seborrheic dermatitis

ICD-10 code

L21.9

ICD-10 code description

Seborrheic dermatitis, unspecified

Primary outcomes**1****Description**

Adherent scalp flaking score (ASFS score)

Timepoint

Before intervention and 1 and 2 months after starting intervention

Method of measurement

Adherent scalp flaking score (ASFS score) formula

Secondary outcomes**1****Description**

Pruritus severity

Timepoint

before intervention and 1 and 2 months after starting intervention

Method of measurement

ItchyQuant itch illustrated numerical rating scale

2**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: Rosemay lotion is applied twice daily on the scalp for two months.

Category

Treatment - Drugs

2

Description

Control group: Ketoconazole 2% lotion is applied twice daily on the scalp for two months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic, Shahid Faghihi hospital

Full name of responsible person

Fatemeh Ale Sana

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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

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Grant name

Grant code / Reference number

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

No

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

Maryam Sadat Sadati

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact
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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