Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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Email address
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

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

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 scientific inquiries

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Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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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