Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing effect of sertaconazole 2% cream versus clotrimazole 1% cream on treatment of seborrheic dermatitis in adult: Double blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of sertaconazole 2% cream versus clotrimazole 1% cream on treatment of seborrheic dermatitis in adult. Design: a double blind randomized clinical trial. Setting and conduct: The eligible patients with seborrheic dermatitis who will refer to Sina Hospital during the study period will be enrolled into the trial. Inclusion criteria: age of 18 to 65 years; seborrheic dermatitis the scalp and face area. Exclusion criteria: pregnancy or breastfeeding; severe seborrheic dermatitis with Itching score greater than 7; treatment with local or systemic corticosteroid, methyldopa, chlorpromazine, or anti-acne drugs during the last month; systemic disease such as Parkinson, AIDS, and mood disorder; sensitivity to drug. Intervention group 1: Sertaconazole 2% cream twice a day for 4 weeks. Intervention group 2: Clotrimazole 1% cream twice a day for 4 weeks. Primary outcome: Number and size of the wound before and 4 weeks after intervention through clinical examination. Randomization The patients will be randomly assigned to the intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701299014N141**
Registration date: **2017-01-29, 1395/11/10**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-01-29, 1395/11/10

Registrant information

Name

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Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of sertaconazole 2% cream versus clotrimazole 1% cream on treatment of seborrheic dermatitis in adult: Double blind randomized clinical trial

Public title

Comparing effect of sertaconazole 2% cream versus

clotrimazole 1% cream on treatment of seborrheic dermatitis in adult

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 18 to 65 years; seborrheic dermatitis the scalp and face area. Exclusion criteria: pregnancy or breastfeeding; severe seborrheic dermatitis with Itching score greater than 7; treatment with local or systemic corticosteroid, methyldopa, chlorpromazine, or anti-acne drugs during the last month; systemic disease such as Parkinson, AIDS, and mood disorder; sensitivity to drug.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization The patients will be randomly assigned to the intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2017-01-28, 1395/11/09

Ethics committee reference number

IR.UMSHA.REC.1395.473

Health conditions studied

1

Description of health condition studied

Seborrheic dermatitis

ICD-10 code

L21.9

ICD-10 code description

Seborrhoeic dermatitis, unspecified

Primary outcomes

1

Description

Number and size of the wound

Timepoint

before and 4 weeks after intervention

Method of measurement

through clinical examination.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Sertaconazole 2% cream twice a day for 4 weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2: Clotrimazole 1% cream twice a day for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Ali Abbas Shabak

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty