

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### 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

Seborrheic 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

**City**

Hamadan

**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

**Contact****Name of organization / entity**

Sina Hospital

**Full name of responsible person**

Dr Ali Abbas Shabak

**Position**

Resident of Dermatology

**Other areas of specialty/work****Street address**

Sina Hospital, Mirzadeh Eshghi Ave.

**City**

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alishabak8@gmail.co

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Sina Hospital

**Full name of responsible person**

Dr Akram Ansar

**Position**

Dermatologist

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## Person responsible for updating data

**Contact****Name of organization / entity**

Department of Epidemiology

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Associate Professor

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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*