

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparsion of efficacy of topical terbinafine 1% cream with topical ketoconazole 2% cream in the treatment of facial seborrhoeic dermatitis

Protocol summary

Summary

This study was designed as a double blind RCT for assessment of efficacy of topical cream of terbinafine and topical cream of ketoconazole comparing to placebo in the treatment of facial seborrhoeic dermatitis. A total of 105 patients with facial seborrhoeic dermatitis attending in dermatologic clinic of sina hospital are recruited and randomly assigned to receive terbinafine, ketoconazole, or placebo twice daily for 4 weeks. The severity of disease and adverse events will be assessed at the baseline and 4th and 12th week after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807202581N1**

Registration date: **2010-10-18, 1389/07/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-10-18, 1389/07/26

Registrant information

Name

Hamide Herizchi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1336 4650

Email address

herizchih@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2011-03-21, 1390/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparsion of efficacy of topical terbinafine 1% cream with topical ketoconazole 2% cream in the treatment of facial seborrhoeic dermatitis

Public title

Efficacy of topical terbinafine 1% cream in the treatment of facial seborrhoeic dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of seborrhoeic dermatitis

Exclusion criteria: application of any treatment that efficient in seborrhoeic dermatitis in last two weeks, presence of AIDS or Parkinson's disease

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Ethics committee of Tabriz University of Medical Sciences, Golgasht street, Tabriz

City

Tabriz

Postal code

Approval date

2010-02-22, 1388/12/03

Ethics committee reference number

9301/4/5

Health conditions studied

1

Description of health condition studied

Seborrhoeic dermatitis

ICD-10 code

L21

ICD-10 code description

Seborrhoeic dermatitis

Primary outcomes

1

Description

Severity of seborrehic dermatitis

Timepoint

baseline, 4th, 12th week

Method of measurement

Global score

Secondary outcomes

1

Description

severity of pruritis

Timepoint

Baseline ,4th, 12th weeks

Method of measurement

severity of pruritus is graded from 0 to 3

2

Description

Severity of erythem

Timepoint

Baseline, 4th, 12th weeks

Method of measurement

severety of erythema is graded from 0 to 3

3

Description

severety of scaling

Timepoint

baseline, 4th, 12th week

Method of measurement

severity of scaling is graded from 0 to 3

4

Description

Side effects

Timepoint

during treatment period

Method of measurement

Erythema or pruritus or burning or contact dermatitis

Intervention groups

1

Description

topical terbinafine 1% cream, twice a day, for 4 weeks

Category

Treatment - Drugs

2

Description

Placebo (topical eucerin cream), twice a day, for 4 weeks

Category

Placebo

3

Description

topical ketoconazole 2% cream, twice a day, for 4 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatologic clinic- Sina hospital

Full name of responsible person

Dr. Hamide Herizchi, Dr Shahla Babainejad, Dr. Sara Saniee

Street address

Sina hospital, Azadi street, Tabriz

City

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mir Ali Eteraf Oskoi

Street address

Tabriz University of Medical Sciences, Golgasht street, Tabriz

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Hamide Herizchi

Position

Assistant Professor-Derrmatologist

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

Sina hospital- Azadi street

City

Tabriz

Postal code**Phone**

+98 41 1336 4650

Fax

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Email

herizchih@TBZMED.ac.ir

Web page address**Person responsible for updating data****Contact****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