Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
+98 33 6459
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