

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the efficacy of oral fluconazole and oral Terbinafine in the treatment of moderate to severe seborrheic dermatitis

Protocol summary

Summary

Aim: To study the efficacy of oral fluconazole compared to oral terbinafine in the treatment of moderate to severe seborrheic dermatitis. Inclusion criteria: Patients with moderate to severe seborrheic dermatitis, filling the consent form, no previous treatment history at least 2 weeks before entering the study such as steroids, antifungal. Exclusion criteria: Lactation, pregnancy, no previous diseases such as renal and liver failure, psoriasis, documented human immunodeficiency virus infection and/or sensitivity to fluconazole and terbinafine. Patients with random allocation were divided into two groups of A and B. In group A 32 patients received fluconazole 300 mg per week for 4 weeks and in group B, we prescribed 32 patients terbinafine 250 mg per day. In the beginning, the seborrheic dermatitis area severity index (SDASI) scoring was calculated and the symptoms were assessed. At first and two and four weeks after treatment tests including CBC, BUN, Cr, AST, ALT, ALK-Ph were requested to monitor drug side effects. After 4 weeks of treatment and two-week posttreatment, all patients are re-examined and evaluated again through SDASI scoring and also symptoms were asked.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102205871N1**

Registration date: **2013-02-05, 1391/11/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-02-05, 1391/11/17

Registrant information

Name

Narges Alizadeh

Name of organization / entity

Gilan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1553 0169

Email address

n_alizadeh@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Gilan University Medical of Sciences

Expected recruitment start date

2008-09-22, 1387/07/01

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of oral fluconazole and oral Terbinafine in the treatment of moderate to severe seborrheic dermatitis

Public title

Comparison of the efficacy of oral fluconazole and oral Terbinafine in the treatment of moderate to severe seborrheic dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with moderate to severe seborrheic dermatitis, filling the consent form, no previous treatment history at least 2 weeks before

entering the study such as steroids, antifungal agents.
Exclusion criteria:Lactation , pregnancy , no pervious diseases such as renal and liver failure, psoriasis, documented human immunodeficiency virus infection and/or sensitivity to fluconazole and terbinafine

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Gilan University of Medical Sciences

Street address

Moavenat Pazhoocheshi -Namjo avenue

City

Rasht

Postal code

Approval date

2009-08-26, 1388/06/04

Ethics committee reference number

1880409102

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

SDASI (Seborrheic dermatitis area severity index)

Timepoint

weeks 4 , 6

Method of measurement

Determine severity of disease by examiner according to SDASI

2

Description

itch

Timepoint

4 weeks later and 6 weeks later

Method of measurement

subjective

Secondary outcomes

1

Description

Side effects

Timepoint

at first,two and four weeks after treatment

Method of measurement

history,physical exam, laboratory tests

Intervention groups

1

Description

Fluconazole 300 mg weekly for four weeks

Category

Treatment - Drugs

2

Description

Terbinafine 250 mg daily for four weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasht Razi hospital

Full name of responsible person

Dr Hamed Monadi Nori

Street address

Razi hospital-Sardarjangal avenue-Entezam square

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gilan University of Medical Sciences

Full name of responsible person

Jalali mir mohammad

Street address

Gilan University of Medical Sciences

City

Rasht

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

Yes

Title of funding source

Gilan 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**

Gilan University of Medical Science

Full name of responsible person

Hamed Monadi Nori MD

Position

Resident of Dermatology

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

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Person responsible for scientific inquiries

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Full name of responsible person

Narges Alizadeh MD

Position

Assistant professor

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Position

Resident of Dermatology

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City

Rasht

Postal code**Phone****Fax****Email****Web page address**

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