Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 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 pervious 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 were 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 scenes

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 Pazhooheshi -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 Sciencse
Full name of responsible person
Hamed Monadi Nori MD
Position
Resident of Dermatology
Other areas of specialty/work
Street address
Razi hospital -Sardarjangal avenue
City
Rasht
Postal code
Phone
+98 13 1554 1001
Fax
+98 13 1553 0169
Email
hamedmonadinori@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gilan University of Medical Sciences
Full name of responsible person
Narges Alizadeh MD
Position
Assistant professor
Other areas of specialty/work
Street address
Razi hospital- Sarderjangal avenue
City
Rasht
Postal code
Phone
+98 13 1554 1001
Fax
Email
n_alizadeh@gums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Gilan University of Medical Sciences
Full name of responsible person
Hamed Monadi Nori MD
Position
Resident of Dermatology
Other areas of specialty/work
Street address
Razi hospital-Sardarjangal avenue
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