

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 previous 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 Pazhooeshi -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 -Sardarjanganl avenue

**City**

Rasht

**Postal code****Phone**

+98 13 1554 1001

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**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- Sarderjanganl avenue

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Rasht

**Postal code****Phone**

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**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**

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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*