

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Comparison of efficacy and safety of oral itraconazole with placebo in the primary treatment and maintenance therapy of moderate to severe seborrheic dermatitis.

#### Protocol summary

##### Summary

The objective of the study is to compare the efficacy of oral itraconazole with placebo in primary and maintenance treatment of moderate to severe seborrheic dermatitis. Inclusion criteria of the study is: Moderate to severe seborrheic dermatitis that will be diagnosed clinically by a dermatologist +/- Recurrent seborrheic dermatitis +/- Seborrheic dermatitis resistant to Topical therapy; no association of seborrheic dermatitis with other papulosquamous dermatoses, Parkinson disease, AIDS, severe renal or liver disease; Age  $\geq 18$ . Patients refer to Razi Hospital diagnosed with seborrheic dermatitis who fulfill the criteria will be assigned codes by the study monitor and patients will be randomly allocated either to receive itraconazole or placebo. Blinding will be maintained until patients completed their last follow up visit. The treatment was administered in two different phases. In the first phase, oral Itraconazole 200mg/day or oral placebo along with topical 1% hydrocortisone ointment once daily and 2% ketoconazole cream twice daily for one week will be used by patients. In the second phase which is maintenance period, oral itraconazole 200mg/day or oral placebo will be given on the first 2 days of every month for 4 months. To determine the sample size, if we consider error as 5% and power of study as 90% and mean difference of improvement in two groups as 2, we require 30 patients for this study. By considering 10% lost to follow up in the study, sample size will be increased to 34 patients in each group. As patients can exit the study as they wish and the study has serial long term follow ups, we may have lost to follow ups more than our expectations.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012091510842N1**

Registration date: **2013-02-18, 1391/11/30**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-02-18, 1391/11/30

##### Registrant information

###### Name

Zaheer Abbas

###### Name of organization / entity

Razi Hospital, Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21556099523

###### Email address

abbas\_z@razi.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2013-02-05, 1391/11/17

##### Expected recruitment end date

2014-05-15, 1393/02/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of efficacy and safety of oral itraconazole

with placebo in the primary treatment and maintenance therapy of moderate to severe seborrheic dermatitis.

**Public title**  
Efficacy of Itraconazole in the treatment of Seborrheic Dermatitis.

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
Inclusion criteria: Moderate to severe seborrheic dermatitis that will be diagnosed clinically by a dermatologist +/- Recurrent seborrheic dermatitis +/- Seborrheic dermatitis resistant to Topical therapy; Age ≥18; Patients willing to take part in the study and expected to be available for the duration of study and comply with study visits. Exclusion criteria: Seborrheic Dermatitis(SD) associated with any other papulosquamous dermatoses like psoriasis, rosacea, lupus erythematosus, lichen planus, tinea, and eczema; Significant renal or liver disease; AIDS; Parkinson Disease; Allergy to azoles; Drug use interfering with itraconazole; Very severe dermatitis defined by erythrodermia or extensive flexural involvement; Use of topical therapy (except moisturizers) and systemic therapy in last 2 week and 1 month, respectively; Pregnancy and lactation.

**Age**  
From **18 years** old to **70 years** old

**Gender**  
Both

**Phase**  
4

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **68**

**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 Tehran University of Medical Sciences

**Street address**  
University central office, 6th floor, Keshavarz Blvd,

Qods Ave, Tehran, Iran.

**City**  
Tehran

**Postal code**

**Approval date**  
2012-09-09, 1391/06/19

**Ethics committee reference number**  
1253

**Health conditions studied**

**1**

**Description of health condition studied**  
Seborrhoeic dermatitis

**ICD-10 code**  
L21

**ICD-10 code description**  
L21 Seborrhoeic dermatitis Excl: Seborrhoea capitis; L21.8 Other seborrhoeic dermatitis L21.9 Seborrhoeic dermatitis, unspecified

**Primary outcomes**

**1**

**Description**  
Signs of disease (Scales and erythema)

**Timepoint**  
At beginning of study, 2 week later, after 1 month, after 2 month, after 3 month and after 4 month.

**Method of measurement**  
Physical examination performed by dermatologist

**2**

**Description**  
Symptoms (Pruritis and burning) severity

**Timepoint**  
At beginning of study, 2 week later, after 1 month, after 2 month, after 3 month and after 4 month.

**Method of measurement**  
Patient history (Questionnaire)

**Secondary outcomes**

**1**

**Description**  
Disease duration

**Timepoint**  
At beginning of study

**Method of measurement**  
History

**2**

**Description**  
Dermatology Life Quality Index

**Timepoint**  
At beginning of study and at the end of study(after 6 month)

**Method of measurement**

Questionnaire

**3****Description**

Seborrheic Dermatitis Area Severity Index

**Timepoint**

At beginning of study, 2 week later, after 1 month, after 2 month, after 3 month, after 4 month and after 6 month.

**Method of measurement**

$(\text{Erythema} + \text{Scales}) \times \text{Local area score} \times \text{Constant of that area (calculated in Questionnaire)}$

**4****Description**

Site of involvement

**Timepoint**

At beginning of study

**Method of measurement**

Physical examination

**5****Description**

Side effects of drug

**Timepoint**

At beginning of study, 2 week later, after 1 month, after 2 month, after 3 month, after 4 month

**Method of measurement**

History and lab tests

**Intervention groups****1****Description**

The treatment will be administered in two different phases. In the first phase, oral Itraconazole 200mg/day along with topical 1% hydrocortisone ointment once daily and 2% ketoconazole cream twice daily for one week will be used by patients. Patients will be advised to apply topical therapy to scalp, face and areas involved. In the second phase which is maintenance period, oral itraconazole 200mg/day will be given on the first 2 days of every month for 4 months.

**Category**

Treatment - Drugs

**2****Description**

In the control group, in the first phase, placebo capsule 200mg/day along with topical 1% hydrocortisone ointment once daily and 2% ketoconazole cream twice daily for one week will be used by patients. Patients will be advised to apply topical therapy to scalp, face and areas involved. In the second phase which is maintenance period, oral placebo 200mg/day will be given on the first 2 days of every month for 4 months.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Razi hospital, Tehran University of Medical Sciences

**Full name of responsible person**

Zaheer Abbas

**Street address**

Razi Hospital, Vahdate Eslami Ave, Vahdate Eslami square, Tehran, Iran

**City**

Tehran

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

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Akbar Fotouhi

**Street address**

Department of Epidemiology and Biostatistics, School of Public Health, Tehran University of Medical Sciences, PO Box: 14155-6446

**City**

Tehran

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

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Zaheer Abbas

**Position**

Resident of dermatology

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

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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## Person responsible for updating data

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**Position**

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## 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*