

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 ≥ 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)

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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**

Seborrheic dermatitis

ICD-10 code

L21

ICD-10 code description

L21 Seborrheic dermatitis Excl: Seborrheic capitis; L21.8 Other seborrheic dermatitis L21.9 Seborrheic 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

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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