Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 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 erythematous, 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
(Erythema+Scales)× Local area score× 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