Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A comparative evaluation of combination therapy of fluconazole 1% and urea 40% compared with fluconazole 1% alone in a nail lacquer for treatment of onychomycosis

Protocol summary

Summary

"The purpose of this study is to assess the safety and efficacy of combination therapy of fluconazole 1% and urea 40% comparing with fluconazole 1% alone in a nail lacquer for treatment of Onychomycosis caused by dermatophytes. In this double- blind study, 70 patients with mycologically confirmed onychomycosis will be randomize into treatment group (fluconazole 1% with urea 40%) or control group (fluconazole 1%) once daily for a maximum of 6 months. All patients should have the clinical diagnosis of distal subungual onychomycosis of the toenails confirmed mycologically by potassium hydroxid (KOH) wet mount and a positive culture for dermatophytes. Patients who have a nail with at least 25% involvement and at least 2 mm of healthy nail from the nail fold to the proximal onychomycotic border will be enrolled in the study. Patients with hypersensitivity to the azole class of compounds; those who have been treated with systemic oral antifungal drugs, Within 3 months, or any investigational drug within one month before enrolling in the study will be excluded. Patients who are clinically cured or improved at the end of therapy will be followed for a 6-month follow-up period and will be assessed at 2, 4, and 6 months after treatment. Patients who are diagnosed as treatment failure at the end of treatment period would not be followed."

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138705301059N1**
Registration date: **2009-02-09, 1387/11/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-02-09, 1387/11/21

Registrant information

Name
Shahindokht Bassiri-Jahromi
Name of organization / entity
Pasteur Institute of Iran
Country
Iran (Islamic Republic of)
Phone
+98 21 6695 3311
Email address
basiri@pasteur.ac.ir

Recruitment status

Recruitment complete

Funding source

Pasteur Institute of Iran

Expected recruitment start date

2008-06-22, 1387/04/02

Expected recruitment end date

2009-08-22, 1388/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative evaluation of combination therapy of fluconazole 1% and urea 40% compared with fluconazole 1% alone in a nail lacquer for treatment of onychomycosis

Public title

"Assessment of the efficacy and safety of combination

therapy of fluconazole 1% and urea 40% comparing with fluconazole 1% alone in the treatment of onychomycosis"

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Presence of at least 25% involvement of the target nail, at least 2 mm of healthy nail from the nail fold to the proximal Dermatophyte onychomycosis border. Exclusion criteria: Non-dermatophytic onychomycosis, hypersensitivity to Azole derivatives, unwilling to sign informed consent, receiving systemic anti-fungal treatment or any investigational drug during three month prior to study

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
randomized, double-blind, parallel controlled trial

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Medical Ethics committee, Pasteur Institute of Iran

Street address
Medical Mycology Department, Pasteur Institute of Iran, Number 69

City
Tehran

Postal code
1316943551

Approval date
empty

Ethics committee reference number
105

Health conditions studied

1

Description of health condition studied
onychomycosis

ICD-10 code
B35.1

ICD-10 code description
Onychomycosis

Primary outcomes

1

Description
Onychomycosis treatment

Timepoint
One month before intervention,and at months 2, 4, and 6 after intervention

Method of measurement
Laboratory Examination

Secondary outcomes

empty

Intervention groups

1

Description
Fluconazole 1% with urea 40% once daily for 6 monthes

Category
Treatment - Drugs

2

Description
Fluconazole 1% once daily for 6 monthes

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Pasteur Institute of Iran, Skin Diseases Centre of Razi Hopital , and Razak company drug production

Full name of responsible person
Shahindokht Basiri Jahromi

Street address
Pasteur Institute, Mycology Department

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pasteur Institute of Iran

Full name of responsible person

Shahindokht Bassiri-Jahromi

Street address

Pasteur Institute of Iran Pasteur street, No. 69

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Pasteur Institute of Iran

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

Pasteur Institute of Iran

Full name of responsible person

Shahindokht Bassiri-Jahromi

Position

head of Mycology Laboratory,Pasteur Institute of Iran,MSc in Medical Mycology

Other areas of specialty/work

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Person responsible for updating data

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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