

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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 randomized 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 hydroxide (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 months

Category

Treatment - Drugs

2

Description

Fluconazole 1% once daily for 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pasteur Institute of Iran, Skin Diseases Centre of Razi Hospital, and Razak company drug production

Full name of responsible person

Shahindokht Basiri Jahromi

Street address

Pasteur Institute, Mycology Department

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Sponsors / Funding sources

1

Sponsor

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Pasteur Institute of Iran
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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
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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