Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of multiple with once-daily nystatin regimens in prevention of oropharyngeal candidiasis in kidney transplant recipients

Protocol summary

Study aim
Comparison of multiple with once-daily nystatin regimens in prevention of oropharyngeal candidiasis in kidney transplant recipients

Design
This open-label clinical trial with parallel-group and phase 3 study will be conducted on 40 patients. Randomization will be performed using Random Allocation software.

Settings and conduct
In this study, kidney transplant patients hospitalized in Urmia Imam Khomeini Hospital will be included in the study. 40 patients will be divided into two equal groups. In one group, patients will receive 30 cc of nystatin once daily, and in the other group, 10 cc three times a day for one month. The study will be conducted without blinding.

Participants/Inclusion and exclusion criteria
Patients undergoing kidney transplantation and treatment with immunosuppressive drugs will be included in the study. The main exclusion criteria are receiving antifungal medication due to fungal infection other than the mouth and throat, intolerance to nystatin, and non-adherence to the prescribed medication regimen.

Intervention groups
Participants in the first group will receive nystatin oral suspension 30 cc once daily for at least one month or until the prednisolone dose is reduced to 10 mg/day or less. Participants in the second group will receive nystatin oral suspension three times daily, 10 mL each time. All patients will instructed to keep the medication in the mouth for at least one minute before swallowing and to avoid eating or drinking for 30 minutes afterward. Nystatin prophylaxis will be done on the first day after transplantation.

Main outcome variables
Oropharyngeal candidiasis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260804070532N1**
Registration date: **2026-08-10, 1405/05/19**
Registration timing: **retrospective**

Last update: **2026-08-10, 1405/05/19**
Update count: **0**

Registration date
2026-08-10, 1405/05/19

Registrant information
Name
Shahram Ghiyasvand
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 44 3198 8003
Email address
ghiyasvand@live.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-23, 1404/06/01

Expected recruitment end date
2025-11-21, 1404/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of multiple with once-daily nystatin regimens in prevention of oropharyngeal candidiasis in kidney transplant recipients

Public title
Comparison of multiple with once-daily nystatin regimens in prevention of oropharyngeal candidiasis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Kidney transplant patients Patients undwrwent immunosuppressive therapy Age over 18 years
Exclusion criteria:
Receipt of systemic antifungal therapy for a fungal infection other than oropharyngeal candidiasis Intolerance to nystatin Non-adherence to the prescribed medication regimen
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible patient's will randomly assigned to two groups using a block randomization method based on computer-generated random numbers produced by the Random Allocation software.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Imam Khomeini Hospital; Urmia University of Medical Sciences
Street address
Imam Khomeini hospital., Ershad Ave., Modarress Blvd., Urmia., Iran.
City
Urmia
Province
West Azarbaijan
Postal code
8135157157
Approval date
2025-12-03, 1404/09/12
Ethics committee reference number
IR.UMSU.HIMAM.REC.1404.101

Health conditions studied

1

Description of health condition studied
oropharyngeal candidiasis
ICD-10 code
B37.89
ICD-10 code description
Other sites of candidiasis

Primary outcomes

1

Description
Occurrence of oropharyngeal candidiasis
Timepoint
First, second, third and fourth weeks after intervention
Method of measurement
Clinical examination

Secondary outcomes

1

Description
Time of development of oropharyngeal candidiasis
Timepoint
First, second, third and fourth weeks after intervention
Method of measurement
Clinical examination

Intervention groups

1

Description
Intervention group: Participants in the first group will receive nystatin oral suspension 30 cc once daily for one month. The patient will hold the medicine in their mouth for at least a minute, then swallow and will not eat anything for half an hour.
Category
Treatment - Drugs

2

Description
Intervention group: Partients in the first group will receive nystatin oral suspension three times daily, 10 mL each time, for one month. The patient will hold the medicine in their mouth for at least a minute, then

swallow and will not eat anything for half an hour.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Imam Khomeini Hospital

Full name of responsible person

Dr. Shahram Ghiyasvand

Street address

Imam Khomeini hospital., Ershad Ave., Modarress Blvd., Urmia., Iran.

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ghiyasvand@live.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Khalkhali

Street address

Urmia University of Medical Sciences., Resalat street., Jahad Blvd., Urmia, Iran.

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5714783734

Phone

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Email

khalkhali.hr@umsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Shahram Ghiyasvand

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No further information available.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The results of the study will be published in the form of a printed article.

When the data will become available and for how long
After the article is published

To whom data/document is available
Researchers

Under which criteria data/document could be used
No further information available.

From where data/document is obtainable
By correspondence with the email address ghiyasvand@live.com

What processes are involved for a request to access data/document
By correspondence with the email address ghiyasvand@live.com

Comments