Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparison of high dose versus low dose of fluconazole for primary prevention of candida infections in patients with hematological malignancies, A single blind prospective randomized clinical trial

Protocol summary

Study aim

Comparison of the effectiveness of high and low dose fluconazole in the primary prevention of candidal infections in patients with hematological malignancies

Design

This study will be conducted as a single-blind prospective clinical trial on 120 patients with hematologic malignancies. Half of the patients will receive a low-dose of oral fluconazole and the remaining half will receive a high-dose of oral fluconazole. daily monitoring routine will be carried out .

Settings and conduct

The study will be carried out on 120 patients with hematologic malignancies and hospitalized in the hematology departments of Shariati Hospital The medicine prescription will be started along with the first course of chemotherapy and the duration of receiving treatment will be continued until the amount of the ANC is less than 10 109 per liter. Data will be collected based on pre-designed questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria, patients over 18 years old , Patients with acute hematological malignancies are candidates for anti,Candida prophylactic regime , patient consent . Exclusion criteria idiosyncratic allergic reaction to azoles , transaminases 10 times more than the normal limit , CrCl less than equal to 50 ml/min , treatment history with systemic anti fungal drugs in the last two weeks ,Pregnancy or breastfeeding - Increased QTc interval , Major clinical interaction (category X)

Intervention groups

A: Patients receive 150 mg of fluconazole once a day (oral tablet). B: patients receive 400 mg of oral fluconazole once a day

Main outcome variables

The number of days of receiving the drug for prophylaxis, - The number of days after which the patient on preventive treatment suffered from a fungal infection, the type of microorganism isolated from the the cultivation environment, The outcome of infection in each group : Death or patient Recovery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140818018842N37**
Registration date: **2023-12-14, 1402/09/23**
Registration timing: **prospective**

Last update: **2023-12-14, 1402/09/23**
Update count: **0**

Registration date

2023-12-14, 1402/09/23

Registrant information

Name

Leyla Sharifi Aliabadi

Name of organization / entity

Research Institute for Hematology, Oncology and Stem Cell Transplantation,Tehran University of Medic

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 3691

Email address

ctu@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-16, 1402/09/25

Expected recruitment end date

2024-06-19, 1403/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of high dose versus low dose of fluconazole for primary prevention of candida infections in patients with hematological malignancies, A single blind prospective randomized clinical trial

Public title

Comparison of high dose versus low dose of fluconazole for primary prevention of candida infections in patients with hematological malignancies, A single blind prospective randomized clinical trial

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Age above 18 years All patients with hematological malignancies can receive a prophylactic regimen against Candida, including: Patients with acute leukemia undergoing primary induction or salvage chemotherapy with the possibility of developing Mucositis Patients with acute leukemia or Myelodysplastic syndromes (MDS) who are expected to experience severe and fatal neutropenia (ANC<500 for more than 7 days) following chemotherapy Having the informed consent of the patient to participate in the study

Exclusion criteria:

Patients with history of idiosyncratic hypersensitivity reaction to azoles Patients with disturbed liver tests with transaminases more than 10 times the normal limit Life expectancy less than 3 weeks History of treatment with systemic antifungal drugs in the last two weeks Patients who have been diagnosed with a fungal infection and are suffering from a fungal infection Pregnancy Patients with increased QTc interval or Torsades de pointes Patients receiving drugs with major clinical interaction (category X) with fluconazole Having a history of invasive fungal infection requiring systemic treatment in the last 6 months Failure to receive fluconazole for more than 3 days during the study Patients with renal failure as CrCl ≤50 mL/min breastfeeding

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study,In order to reduce bias, randomization is done by online randomization method by a statistician. the randomization process was conducted using the Clinical Trial Randomization Tool provided by the National Cancer Institute (NCI) https://ctrandomization.cancer.gov/ to assign 120 participants to two groups: Group A and Group B. This randomization procedure was performed in a double-blind manner, ensuring that both investigators and participants remained unaware of the group assignments, and the randomization process was blinded. Then, in order to reduce to zero the possibility of interfering in the selection of the intervention group by the researcher, 120 envelopes (containing number 1 to 120 and intervention group A or B) were prepared at the time of the start of the study based on the order of entry of the eligible participants into the study, randomly from one of the envelopes was sent to The order will be opened and the placement of the patient in the intervention group will be determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will be placed in one of two study groups and will be blinded to which study group they will be placed in. The drug is delivered to the patient by the researcher. And the nurses will be blind to which study group they are included in.

Placebo

Not used

Assignment

Other

Other design features

This study will be conducted as a prospective, single-blind clinical trial on patients with hematological malignancies and hospitalized in the hematology departments of Shariati Hospital affiliated to Tehran University of Medical Sciences

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Institute of Pharmaceutical Sciences -Tehran University of Medical Sciences

Street address

Poursina St., Tehran University of Medical Sciences, Faculty Pharmacy, Institute of Pharmaceutical Sciences (TIPS)

City

tehran

Province

Tehran

Postal code

14176-13151

Approval date
2022-07-17, 1401/04/26
Ethics committee reference number
IR.TUMS.TIPS.REC.1401.040

Health conditions studied

1

Description of health condition studied
Occurrence of candidal infections (candidal colonization, superficial fungal infection, systemic fungal infection) in hematological malignancies,
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The number of days receiving medicine for prophylaxis - the number of days the patient has been infected on preventive treatment.
Timepoint
daily monitoring
Method of measurement
Questionnaire (checking the number of days)

Secondary outcomes

1

Description
The type of organism isolated from the culture (fungus)
Timepoint
It varies according to the patient's condition.
Method of measurement
72 hours after an unexplained fever in a patient, despite the start of antibiotic therapy, a sample is sent for culture from blood, urine, and tissues suspected of fungal infection, and if the microorganism grows, the strain is isolated and identified.

2

Description
the number of days that the patient has complications after taking the drug
Timepoint
daily monitoring
Method of measurement
Questionnaire (checking the number of days the patient has complications with the drug)

3

Description
the type of complications with drug
Timepoint
daily monitoring
Method of measurement
Questionnaire (checking the type of complication caused by the drug)

4

Description
The outcome of infection: death or patient recovery
Timepoint
daily monitoring
Method of measurement
Questionnaire (daily examination of the patient's clinical and laboratory conditions and the survival report of the patient on the days they receive the drug)

Intervention groups

1

Description
Intervention Group A: Patients receiving a low dose of oral fluconazole 150 mg once a day.
Category
Treatment - Drugs

2

Description
Intervention group B: Patients receiving a high dose of oral fluconazole 400 mg once a day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hematology departments of Shariati Hospital
Full name of responsible person
Bita Shahrami
Street address
Kargar Shomali Ave, Shariati Hospital, Tehran, 14117-13135 I.R. Iran
City
tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 2635
Fax
+98 21 8800 4140
Email
bita.shahrami@gmail.com
Web page address
https://www.riohct.ir/RIOHCT/fa/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Institute for Oncology, Hematology and Cell Therapy

Full name of responsible person
Mohammad Vaezi

Street address
Kargar Shomali Ave, Shariati Hospital, Tehran, 14117-13135 I.R.Iran

City
tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 8490 2635

Fax
+98 21 8800 4140

Email
horcbmt@tums.ac.ir

Web page address
https://www.riohct.ir/RIOHCT/en/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Research Institute for Oncology, Hematology and Cell Therapy

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
Tehran University of Medical Sciences

Full name of responsible person
roghayeh savary kouehkonan

Position
Resident of Pharmacotherapy

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

Street address
Kargar-e-shomali Ave, Shariati Hospital

City
tehran

Province
Tehran

Postal code
1411713131

Phone
+98 21 8490 2635

Fax
+98 21 8800 4140

Email
rsavary72@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Bita Shahrami

Position
Assistant Professor of Critical Care Pharmarcotherapy

Latest degree
Subspecialist

Other areas of specialty/work
Medical Pharmacy

Street address
Kargar Shomali Ave, Shariati Hospital, Tehran, 14117-13135 I.R.Iran

City
Tehran

Province
Tehran

Postal code
1411713131

Phone
+98 21 8490 2635

Fax
+98 21 8800 4140

Email
bita.shahrami@gmail.com

Web page address
https://www.riohct.ir/RIOHCT/en/

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Leyla Sharifi Aliabadi

Position
Nurse

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Kargar-e-Shomali Ave., Shariati Hospital

City
tehran

Province
Tehran

Postal code

1411713131

Phone

+98 21 8490 2635

Fax

+98 21 8800 4140

Email

l-sharifi@tums.ac.ir

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

There is no further information.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available