

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Efficacy of Fluconazole in comparison with Nystatin in the prevention of fungal infections in very low birth weight infants

#### Protocol summary

##### Study aim

Comparison of the effect of injectable and oral fluconazole with oral Nystatin in the prevention of fungal infections in preterm infants

##### Design

A clinical trial with parallel groups, one-blind, randomized (permuted block randomization), phase 3 on 50 newborns, using www.sealedenvelope.com for randomization

##### Settings and conduct

This study is performed in the NICU of Alzahra Hospital in Tabriz. Newborns are randomly assigned to two groups. In the first group, newborns receive injectable or oral fluconazole. In the second group, newborns receive oral nystatin. In this study, the subjects did not know the type of drug received.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Premature newborns with gestational age less than 32 weeks, Newborn in the age range of 0 to 3 days, Birth weight less than 1500 gr Parents' consent to participate in the study Exclusion Criteria: Neonates with congenital anomalies, Newborns with shock

##### Intervention groups

In the first intervention group, newborns receive injected fluconazole (manufactured by Sina Daru, Iran) at a dose of 3 mg/kg twice a week and in case of peripheral or central venous rupture, continue with oral fluconazole 6 mg/kg twice a week for four weeks. In the second intervention group: newborns receive oral nystatin (manufactured by Emad Darman Pars, Iran) in the amount of one hundred thousand units (1 ml) as a suspension every eight hours for four weeks.

##### Main outcome variables

Fungal infections

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210908052412N1**  
Registration date: **2021-10-27, 1400/08/05**  
Registration timing: **registered\_while\_recruiting**

Last update: **2021-10-27, 1400/08/05**

Update count: **0**

##### Registration date

2021-10-27, 1400/08/05

##### Registrant information

##### Name

Leila Asgarzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2304 6253

##### Email address

asgarzadeh.l@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-10, 1400/03/20

##### Expected recruitment end date

2021-11-11, 1400/08/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of Fluconazole in comparison with Nystatin in the prevention of fungal infections in very low birth weight infants

## Public title

Efficacy of Fluconazole in comparison with Nystatin in the prevention of fungal infections in very low birth weight infants

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Premature newborns with gestational age less than 32 weeks Newborn in the age range of 0 to 3 days Birth weight less than 1500 gr Parents' consent to participate in the study

### Exclusion criteria:

Neonates with congenital anomalies Newborns with shock

## Age

From **1 day** old to **3 days** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this study, the block randomization method is used with blocks of sizes six and four. The website <https://www.sealedenvelope.com> is used to create a randomization list. The blocks are randomly selected using this website and given to a researcher who is not involved in choosing the type of drug. Each random chain generated contains a unique code for concealment. The drug regimen is placed in envelopes according to random chains, and after sealing it on the envelopes, the specific number created by the site is written and the envelopes are randomly placed in a box. a box.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In this study, only newborns are blind (due to the condition of the infant and the parents do not know what drug is given to the infant) and do not know the type of medication received.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

#### Street address

3rd Floor, Central Building, Azadi St, Golgasht St

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166614766

### Approval date

2021-05-03, 1400/02/13

### Ethics committee reference number

IR.TBZMED.REC.1400.144

## Health conditions studied

## 1

### Description of health condition studied

Fungal Infections, Premature

### ICD-10 code

P37.5

### ICD-10 code description

Neonatal candidiasis

## Primary outcomes

## 1

### Description

Fungal infections

### Timepoint

Baseline and end of study (after 4 weeks)

### Method of measurement

Bactec, cerebrospinal fluid (CSF) or urine culture

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: Receiving injectable fluconazole (made by Sina Daru, Iran) at a dose of 3 mg/kg twice a week and in case of peripheral or central vein rupture, continue with oral fluconazole 6 mg / kg twice a week for 4 weeks .

### Category

Treatment - Drugs

## 2

### Description

Intervention group: Receiving oral nystatin (Emad

Darman Pars, Iran) 100,000 units (1 ml) in suspension every eight hours for four weeks

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Alzahra Hospital

**Full name of responsible person**

Leila Asgarzadeh

**Street address**

Artesh Street, Alzahra Hospital,

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138663134

**Phone**

+98 41 3553 9161

**Email**

dr.l.asgarzadeh@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mohammad Samiei

**Street address**

3rd Floor, Central Building, Tabriz University of Medical Science, Golgasht St,

**City**

Tabriz

**Province**

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**Postal code**

5166616471

**Phone**

+98 41 3336 3767

**Email**

Samiei.moh@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Leila Asgarzadeh

**Position**

Fellow

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

**Street address**

No. 23, Forozanfar St, Gisha St

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**Postal code**

1446754471

**Phone**

0098 23046253

**Email**

dr.l.asgarzadeh@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

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**Person responsible for updating data**

**Contact**

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0098 23046253

**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

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

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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