

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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 fluoxonazole 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,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

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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

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

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Position

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Specialist

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Person responsible for updating data

Contact

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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