Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 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

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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 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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Tabriz

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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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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

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Person responsible for scientific inquiries

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Position
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Latest degree
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