

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Effectiveness of Intravenous Fluconazole prophylaxis on clinical outcome of preterm neonates during hospitalization

Protocol summary

Summary

systemic fungal infections is one of the most common causes of the mortality especially in preterm neonates . The aim of this study is the evaluation of the effect of Intravenous Fluconazole prophylaxis on clinical outcome of preterm neonates during hospitalization . Methods and materials: In a nonrandomized , single-blind clinical trial , without placebo 100 preterm neonates with a birth weight less than 1250 g who had no major congenital anomalies , and alive until three days after birth , enrolled into the study. 50 neonates selected as case group , and 50 neonates as control group alternatively . During hospitalization , first group received 6-weeks treatment with 3mg/kg dose of fluconazole as once every 3 days in first 2 weeks , once every 2 days in second 2 weeks and every day in third 2 weeks and NICU standard care(including IV line , antibiotics and respiratory care) , but control group received only NICU standard care. The outcomes include duration of mechanical ventilation , in-hospital mortality and the time of hospitalization . The data from two groups were analyzed using appropriate statistical tests .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051411499N1**

Registration date: **2014-08-03, 1393/05/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-03, 1393/05/12

Registrant information

Name

Abdollah Jannatdoust

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1526 2250

Email address

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2013-08-24, 1392/06/02

Expected recruitment end date

2014-02-24, 1392/12/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Intravenous Fluconazole prophylaxis on clinical outcome of preterm neonates during hospitalization

Public title

Intravenous Fluconazole prophylaxis in preterm neonates

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : birth weight less than 1250 g

Exclusion criteria: 1- major congenital anomalies 2- death in three days of life

Age

From **1 day** old to **29 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single 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 Research Vice- Cancellor of Tabriz University of Medical Sciences

Street address

3 rd floor , 2nd central building of TBZmed , Golgasht Ave.

City

Tabriz

Postal code

5174816671

Approval date

2013-08-21, 1392/05/30

Ethics committee reference number

9279

Health conditions studied**1****Description of health condition studied**

Candidial sepsis

ICD-10 code

P37.5

ICD-10 code description

Neonatal candidiasis

Primary outcomes**1****Description**

Hospital stay days

Timepoint

measured at discharge

Method of measurement

in hospital days

2**Description**

Assisted ventilation duration in days

Timepoint

measured at discharge

Method of measurement

days under assisted ventilation

Secondary outcomes**1****Description**

Mortality Rate

Timepoint

after death

Method of measurement

if died

Intervention groups**1****Description**

Intravenous fluconazole 3mg/kg for 6-weeks treatment with 3mg/kg dose of fluconazole as once every 3 days in first 2 weeks, once every 2days in second 2 weeks and every day in third 2 weeks

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Hasan Soleinpour

Street address

Artesh ave.Baghshomal crossroad

City

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Vice-Cancellor of Tabriz University of Medical Sciences

Full name of responsible person

Abdollah Jannatdoust

Street address

Alzahra hospital , Baghshomal Crossroad

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Vice-Cancellor of Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abdollah Jannatdoust

Position

Assistant professor/Neonatology subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty