

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Effect of fluconazole in the prevention of infection in neonates with birth weight under 1200 grams admitted to neonatal intensive care unite

Protocol summary

Study aim

Study of administration of intravenous fluconazole in the prevention of infection in neonates with birth weight under 1200 grams admitted to neonatal intensive care unite

Design

Clinical trial with control group, intervention on September 15, 2016 was started for all newborns, and the control group was selected from of neonates born before this date.

Settings and conduct

The study will be conducted in neonatal intensive care unit in Izadi Hospital of Qom on infants weighing less than 1200 gr. The outcomes associated with intervention (including sepsis, pneumothorax and ...), will be evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: neonates with birth weight under 1200 grams, admitted to neonatal intensive care unite.

Exclusion criterion: major congenital anomalies

Intervention groups

Control group: routine care. Intervention group: Fluconazole, intravenous, 3 mg/kg, twice a week until the first 6 weeks of life.

Main outcome variables

Sepsis; pneumothorax

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170215032587N4**

Registration date: **2018-11-10, 1397/08/19**

Registration timing: **retrospective**

Last update: **2018-11-10, 1397/08/19**

Update count: **0**

Registration date

2018-11-10, 1397/08/19

Registrant information

Name

Mohammad Aghaali

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-10-22, 1394/07/30

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

2015-10-22, 1394/07/30

Actual recruitment end date

2017-10-22, 1396/07/30

Trial completion date

2017-10-22, 1396/07/30

Scientific title

Effect of fluconazole in the prevention of infection in neonates with birth weight under 1200 grams admitted to neonatal intensive care unite

Public title

Fluconazole in the prevention of infection in neonates

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Neonates with birth weight under 1200 grams Admitted to neonatal intensive care unite

Exclusion criteria:

Major congenital anomalies

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Not randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Qom University of Medical Sciences

Street address

No. 83, Alley 4, Alley 1.1, Safashahr Street, Qom

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Province

Ghous

Postal code

3716987366

Approval date

2017-10-03, 1396/07/11

Ethics committee reference number

IR.MUQ.REC.1396.87

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

Candidiasis

ICD-10 code

B37

ICD-10 code description

Candidiasis

2**Description of health condition studied**

Sepsis

ICD-10 code

A41

ICD-10 code description

Other sepsis

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

Sepsis

Timepoint

6 weeks after intervention

Method of measurement

Clinical symptoms and blood culture

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

Pneumothorax

Timepoint

6 weeks after intervention

Method of measurement

Chest X-ray

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

Control group: Routine care

Category

Prevention

2**Description**

Intervention group: Fluconazole, IV, 3 mg/kg, twice a week until the first 6 weeks of life

Category

Treatment - Drugs

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

Izadi hospital

Full name of responsible person

Parvaneh Sadeghi-moghaddam

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Izadi hospital, Azar Ave, Qom

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Sponsors / Funding sources

1

Sponsor

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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
Ghous 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

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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
The data are specific to this study
Study Protocol
No - There is not 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
No - There is not a plan to make this available