Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

Phone
+98 912 751 5639

Email address
maghaali@muq.ac.ir

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
City
Qom
Province
Ghoum
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
Street address
Izadi hospital, Azar Ave, Qom
City
Qom
Province

Ghoum
Postal code
3715888566
Phone
+98 25 3721 1301
Email
Psadeghi@muq.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Hossein Saghafi
Street address
No. 83, Alley 4, Alley 1.1, Safashahr Street, Qom
City
Qom
Province
Ghoum
Postal code
3716987366
Phone
+98 25 3285 2720
Email
hsaghafi@muq.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Mohammad Aghaali
Position
Medical Doctor
Latest degree
Medical doctor
Other areas of specialty/work
Epidemiology
Street address
Qom University of Medical Science, Saheli Street, Qom
City
Qom
Province
Ghoum
Postal code
3713649373
Phone
+98 25 3285 2720
Fax
+98 25 3285 8464
Email
maghaali@muq.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Parvaneh Sadeghi-moghadam
Position
Assistance professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Qom University of Medical Science, Saheli Street, Qom
City
Qom
Province
Ghoum
Postal code
3713649373
Phone
+98 25 3285 2720
Fax
+98 25 3285 8464
Email
md_sadeghimoghadam@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Mohammad Aghaali
Position
Medical Doctor
Latest degree
Medical doctor
Other areas of specialty/work
Epidemiology
Street address
Qom University of Medical Science, Saheli Street, Qom
City

Qom
Province
Ghoum
Postal code
3713649373
Phone
+98 25 3285 2720
Fax
+98 25 3285 8464
Email
maghaali@muq.ac.ir

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