

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Oral nystatin prophylaxis to prevent of candida colonization in premature infant with weight less than 1500 gram in Neonatal Intensive care Unit

Protocol summary

Study aim

Oral nystatin prophylaxis in preventing Candida colonization

Design

A clinical trial with a control group, not blinded, randomized by random sequencing on 106 patients.

Settings and conduct

All infants born in Ayatollah Mousavi Hospital in Zanjan or admitted to other hospitals in the province who are in the first 72 hours of life and have a gestational age less than 32 weeks or birth weight less than 1500 gram, they enter one of the control or intervention groups and then, based on the prepared checklist, information about the variables is recorded and evaluated.

Participants/Inclusion and exclusion criteria

Infant born in the first 72 hours of life have a gestational age less than 32 weeks or a birth weight less than 1,500 grams will be examined after obtaining written and informed consent from the parents. Infants who have severe abnormalities or chromosomal abnormalities, severe sepsis, Congenital heart disease, Intraventricular hemorrhage, disseminated intravascular coagulation, tracheal diseases requiring surgery, fungal infections proven or parental disagreement are excluded from the study.

Intervention groups

Infants in the nystatin group receive 100,000 UI / ml, 0.5 ml intraorally and 0.5 ml via the orogastric tube three times a day from the nystatin oral suspension of Emad Darman Pars Company. The control group did not receive antifungal prophylaxis. After one week, it is prepared from the oral and rectal mucosa by sterile swap method and sent to the laboratory for smear, culture and analysis.

Main outcome variables

Gestational age, birth weight, Type of delivery, prolonged premature rupture of the Membrane, use of broad-spectrum antibiotics, receiving invasive ventilation, Duration of receiving invasive ventilation, Oral

culture and smear according to the candida, rectal culture and smear according to the candida,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201222049802N2**

Registration date: **2021-03-15, 1399/12/25**

Registration timing: **prospective**

Last update: **2021-03-15, 1399/12/25**

Update count: **0**

Registration date

2021-03-15, 1399/12/25

Registrant information

Name

Asghar Marzban

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 1292

Email address

drmarzban@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-05-05, 1400/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Oral nystatin prophylaxis to prevent of candida colonization in premature infant with weight less than 1500 gram in Neonatal Intensive care Unit

Public title

Oral nystatin prophylaxis to prevent of candida colonization in premature infant with weight less than 1500 gram in Neonatal Intensive care Unit

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

infants born in the first 72 hours of life birth weight less than 1500gram gestational age less than 32 weeks who are hospitalized in the neonatal intensive care unit

Exclusion criteria:

severe abnormalities chromosomal abnormalities severe sepsis Congenital heart disease Intraventricular hemorrhage disseminated intravascular coagulation Thrush congenital disorders requiring surgery Fungal infections proven by blood or urine culture require treatment with appropriate antifungal drugs such as amphotericinCommunity Verified icon Parents' dissatisfaction with the infant's participation in the study

Age

From **1 day** old to **3 days** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **106**

More than 1 sample in each individual

Number of samples in each individual: **2**

One week after birth, a swab is prepared from the oral and rectal mucosa for smear and culture of the fungus and sent to the laboratory of Mousavi Hospital in Zanjan for analysis.

Randomization (investigator's opinion)

Randomized

Randomization description

Random sequence through a table of random numbers

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Infants are randomly divided into one of two groups, the nystatin group and the control group. Infants in both groups are similar in age, sex, gestational age, weight, and other anthropometric findings. Infants in the nystatin group receive 100,000 UI / ml, 0.5 ml intraorally and 0.5 ml via the urogastric tube three times a day from the

nystatin oral suspension of Emad Darman Pars Company. The control group did not receive antifungal prophylaxis.

Secondary Ids

empty

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

Ethics committee of Zanjan University of Medical Sciences

Street address

Ayatollah Mousavi Hospital, Above Shahid Sabouti Boulevard, Gavazang Road, Zanjan, Iran.

City

Zanjan

Province

Zanjan

Postal code

4513956183

Approval date

2020-12-16, 1399/09/26

Ethics committee reference number

IR.ZUMS.REC.1399.330

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

candida colonization

ICD-10 code

P37.5

ICD-10 code description

Neonatal candidiasis

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

Gestational age

Timepoint

Week

Method of measurement

The number of weeks that have elapsed since the last menstrual period.

2**Description**

Birth weight

Timepoint

Birth

Method of measurement

Weighing the baby

3

Description

Type of delivery(Natural vaginal delivery or cesarean section)

Timepoint

at birth

Method of measurement

Get a history and file

4

Description

Premature rupture of the membrane

Timepoint

rupture of the membrane>18houres

Method of measurement

Get a history and file

5

Description

Use of broad-spectrum antibiotics (third-generation cephalosporins and carbapenems)

Timepoint

One week after birth

Method of measurement

Get a history and file

6

Description

Receive invasive respiratory ventilation

Timepoint

One week after birth

Method of measurement

Get a history and file

7

Description

oral culture and smear for fungi

Timepoint

one week after birth

Method of measurement

laboratory report

8

Description

rectal culture and smear for fungi

Timepoint

One week after birth

Method of measurement

laboratory report

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Infants born in Ayatollah Mousavi Hospital in Zanjan or admitted from other hospitals in the province who are in the first 72 hours of life and are admitted to the neonatal intensive care unit and have a gestational age less than 32w or birth weight less than 1500gr, From the oral suspension of nystatin of Emad Darman Pars Company, they receive 100,000 UI / ml, 1ml (0.5 ml into the oral cavity and 0.5 ml through the urogastric tube) three times a day. The mouth and rectum are prepared for smear and fungal culture and sent to the laboratory of Mousavi Hospital in Zanjan for analysis.

Category

Prevention

2

Description

Control group: Control group: Intervention group: Infants born in Ayatollah Mousavi Hospital in Zanjan or admitted from other hospitals in the province who are in the first 72 hours of life and are hospitalized in the neonatal intensive care unit and have a gestational age less than 32w or birth weight less than 1500gr, the control group does not receive antifungal prophylaxis. After a week, a swab is prepared from the oral mucosa and rectum for smear and culture of the fungus and sent to the laboratory of Mousavi Hospital in Zanjan for analysis.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi hospital

Full name of responsible person

Samie Ahadi

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Ayatollah Mousavi Hospital, Gavazang Road, Above Shahid Sabouti Boulevard, zanjan, iran.

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Email

Mousavihospital@zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Alireza Shoghli

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Ayatollah Mousavi Hospital, Above Shahid Sabouti Boulevard, Gavazang Road, zanjan, iran.

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Email

Mousavihospital@zums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Zanjan University Of Medical Science

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**

Zanjan University of Medical Sciences

Full name of responsible person

Asghar Marzban

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Asghar Marzban

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact**Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Asghar Marzban

Position

Professor

Latest degree

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

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