

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparative study of the effect of concomitant use of Lactobacillus Ramnosus probiotic and oral antifungal nystatin on inhibitory intestinal colony growth in Candida albicans in infants under 2500 g

Protocol summary

Study aim

Comparative study of the effect of concomitant use of Lactobacillus Ramnosus probiotic and oral antifungal nystatin on inhibitory intestinal colony growth in Candida albicans in infants under 2500 g

Design

This study is a double-blind clinical trial with a parallel design and a control group. The study population will include all infants weighing less than 2500 grams hospitalized in Mohammad Kermanshahi Hospital. 100 eligible babies will be selected conveniently. For randomization, permutation block is used and participants are assigned to intervention and control groups.

Settings and conduct

This study, which will be performed in Mohammad Kermanshahi Hospital, is a double-blinded one. Participants and statistical analysts are unaware of the allocation of the intervention and control group. Samples are processed in the laboratory within two hours and cultured in a general medium such as sabrodextrose agar. Two candida culture samples are taken from each infant from the stool (the first sample at 1 to 3 days of age and before the start of medication, and the second sample 7 days later).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Birth weight 2500 grams and less; Age of hospitalization time 72 hours and less Exclusion criteria: Maternal use of oral and topical antifungals during the last month of pregnancy

Intervention groups

The intervention group will receive 10 drops of nystatin 100,000 oral units 3 times a day along with 10 oral drops of Ramnoflor (Lactobacillus Ramnosus) in the mouth once a day (4 times in total). The control group will receive 10 drops of placebo (distilled water) 4 times a day.

Main outcome variables

Duration of hospitalization; Necrotizing enterocolitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N175**

Registration date: **2021-09-25, 1400/07/03**

Registration timing: **prospective**

Last update: **2021-09-25, 1400/07/03**

Update count: **0**

Registration date

2021-09-25, 1400/07/03

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

foroughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-02, 1400/07/10

Expected recruitment end date

2022-01-30, 1400/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of concomitant use of Lactobacillus Ramnosus probiotic and oral antifungal nystatin on inhibitory intestinal colony growth in Candida albicans in infants under 2500 g

Public title

the effect of concomitant use of Lactobacillus Ramnosus probiotic and oral antifungal nystatin on inhibitory intestinal colony growth in Candida albicans in infants under 2500 g

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Birth weight 2500 grams and less Age of hospitalization time 72 hours and less

Exclusion criteria:

Maternal use of oral and topical antifungals during the last month of pregnancy

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

For random allocation, permuted block randomization method is used to balance the number of samples assigned to each of the study groups. This method is done by selecting blocks with the size of each quadruple block (2 participants in the intervention group and 2 participants in the control group) and each of the 6 possible cases of numbers for the quad block is assigned as follows: 1) AABB 2) ABAB 3) ABBA 4) BBAA 5) BABA 6) BAAB. Using a table of random numbers, the numbers between 1 and 6 are selected and in accordance with each number, the allocation list of the intervention or control group will be determined, thus sampling will continue until the end of the samples.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants and statistical analysts are unaware of the nature of control or intervention of groups A and B. Medications can only be identified by the serial number on the container. The serials are with the main researcher and will remain confidential until the end of the study

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2021-08-31, 1400/06/09

Ethics committee reference number

IR.KUMS.REC.1400.426

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**

Duration of hospitalization

Timepoint

End of study (10 days after starting the study)

Method of measurement

According to documents

2**Description**

Necrotizing enterocolitis

Timepoint

End of study (10 days after starting the study)

Method of measurement

Based on the doctor's diagnosis

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive 10 drops of nystatin 100,000 oral units 3 times a day along with 10 oral drops of Ramnoflor (Lactobacillus Ramnosus) in the mouth once a day (4 times in total).

Category

Treatment - Drugs

2

Description

The control group will receive 10 drops of placebo (distilled water) 4 times a day.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammad Kermanshahi Hospital

Full name of responsible person

Farzad Mashreghi

Street address

Mohammad Kermanshahi Hospital, Helal Ahmar
Crossroad

City

Kermanshah

Province

Kermanshah

Postal code

6713733135

Phone

+98 83 3721 8202

Email

farzadmashreghi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Khodarahmi

Street address

Vice Chancellor for Research Affairs, Kermanshah
University of Medical Sciences, Building No.2, Shahid
Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

rkhodarahmi@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Farzad Mashreghi

Position

Resident of Children

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Mohammad Kermanshahi Hospital, Helal Ahmar
Crossroad

City

Kermanshah

Province

Kermanshah

Postal code

6713733135

Phone

+98 83 3721 8202

Email

farzadmashreghi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Maziar Vakili Amini

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Mohammad Kermanshahi Hospital, Helal Ahmar Crossroad

City

Kermanshah

Province

Kermanshah

Postal code

6713733135

Phone

+98 83 3721 8205

Email

mzvakilia@ac.ir .com

Other areas of specialty/work

Pediatrics

Street address

Mohammad Kermanshahi Hospital, Helal Ahmar Crossroad

City

Kermanshah

Province

Kermanshah

Postal code

6713733135

Phone

+98 83 3721 8202

Email

farzadmashreghi@gmail.com

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

There is no more information

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

Person responsible for updating data**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Farzad Mashreghi

Position

Resident of Children

Latest degree

Medical doctor