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)
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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
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Mohammad Kermanshahi Hospital, Helal Ahmar Crossroad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
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Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard
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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
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
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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
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