Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of probiotics on late-onset sepsis in very preterm newborns

Protocol summary

Study aim

In the event of probiotics effect in prevention of late-onset sepsis, we will use it in neonatal and NICU wards as a standard prevention strategy.

Design

A randomized,triple blinded,placebo controlled clinical trial with two parallel groups, randomize blocking designed of 84 preterm infants born at < 32 weeks' gestation weighing 1000- 1500 gr classified into two groups of 42 intervention and control groups ,enrolled between February 2017 and September 2017

Settings and conduct

This study was a Triple-Blind placebo controlled clinical trial done in Urmia Shahid Motahari Hospital,between February 2017 and September 2017 .84 preterm infants born at < 32 weeks' gestation weighing 1000- 1500 g and matched with clinical inclusion criteria for the study randomly assigned. Group A, recived one drop per kilogram of body weight of probiotic solution twice daily and Group B, received Dish water one drop per kilogram of body weight twice daily.The primary outcome was the incidence of at least one episode of definite late onset sepsis before 40 weeks corrected age or discharge home.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: 1. Preterm infants weighting 1000-1500 g and less than 32 weeks' gestational age at birth 2. Enrolled within 48 hours of birth Exclusion criteria:1- Major congenital anomalies(Esophageal atresia,Omphalocele,Imperforate anus)2- Major congenital heart malformations3-Genetic anomalies(e.g Trisomy 21 or other trisomies)4- Considered likely to die within 72 hours of birth 5-Death befor minimal entral feeding(10-20cc/kg/day)6-Parents from whom informed consent cannot be obtained.7- Sepsis in admission(CRP>10mg/dl in 1th day of admission)8-Asphyxia (grade II, III)9-Maternal chorioamnionitis

Intervention groups

Very low-birth-weight preterm infants with a gestational age of less than 32 weeks and a weight of 1000-1500 gr who are admitted to the NICU of Shahid Motahari Hospital in Urmia during the first 48 hours of their birth .Patients are randomly divided into two groups; the intervention group recive probiotic and the control group receive Dish water as placebo.

Main outcome variables

Late onset sepsis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171218037936N1**
Registration date: **2018-03-05, 1396/12/14**
Registration timing: **retrospective**

Last update: **2018-03-05, 1396/12/14**
Update count: **0**

Registration date

2018-03-05, 1396/12/14

Registrant information

Name
Kamran Dehghan

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 44 3365 4154

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date
2017-09-22, 1396/06/31
Actual recruitment start date
2017-02-19, 1395/12/01
Actual recruitment end date
2017-09-22, 1396/06/31
Trial completion date
empty

Scientific title
Evaluation of the effect of probiotics on late-onset sepsis in very preterm newborns

Public title
Evaluation of the effect of probiotics on late-onset sepsis in very preterm newborns
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Preterm infants weighting 1000-1500 g and less than 32 weeks' gestational age at birth Enrolled within 48 hours of birth
Exclusion criteria:
Major congenital anomalies(Esophageal atresia,Omphalocele,Imperforate anus) Major congenital heart malformations Genetic anomalies(e.g Trisomy 21 or other trisomies) Considered likely to die within 72 hours of birth Death before minimal entral feeding(10-20cc/kg/day) Parents from whom informed consent cannot be obtained Sepsis in admission(CRP>10mg/dl in 1st day of admission) Asphyxia (grade II, III) Maternal chorioamnionitis
Age
From **1 day** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **84**
Actual sample size reached: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
randomization will be as balanced (permuted) block randomization. Sample size was determined based on previous studies with respect to d = 10% and P = 0.7 and α = 0.05 in each group of 42 people in a total of 84 people. According to the sample size, and block size of 6 (AAABBB), 14 blocks will be selected. Initially, all possible six-point permutations will be listed, and then each will be assigned a code, and in the sequel, 14 of these codes will be selected as lotteries, followed by the corresponding combinations with each of the selection codes Listed and individuals will be assigned to the corresponding groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The groups under study are two groups .The probiotic will be used for intervention group and placebo for the control group. Each participant will be assigned a code that will remain secret until the end of the study. To ensure that the type of substance received are not identified, a placebo and probiotic substance will be provided in one form and in the same vials .
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Urmia University of Medical Sciences
Street address
Urmia university of medical sciences-Resalat Blvd-Emergency Alley. Urmia Vest Azarbaijan Iran, Islamic Republic Of
City
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Province
West Azarbaijan
Postal code
5714783734
Approval date
2017-02-08, 1395/11/20
Ethics committee reference number
ir.rec.umsu.1395.480

Health conditions studied

1

Description of health condition studied
late-onset sepsis in very preterm infants
ICD-10 code
P36.9
ICD-10 code description
Bacterial sepsis of newborn, unspecified

Primary outcomes

1

Description
Late-onset sepsis

Timepoint
Baseline(admission), weekly and when clinical sepsis suspected
Method of measurement
Measurement of C-Reactive Protein and clinical clinical evaluation

Secondary outcomes

1

Description
Necrotizing enterocolitis
Timepoint
On admission, every week, when symptoms of Necrotizing enterocolitis are diagnosed
Method of measurement
Clinical evaluation based on Bell's Criteria

2

Description
Duration of primary hospitalization
Timepoint
Time of discharge
Method of measurement
Count the number of hospitalization days

3

Description
The number of days the infant takes to complete entral feeding(120mL/kg per day)
Timepoint
During the study period
Method of measurement
number of days until an infant to eat 120mL / kg per day of milk.

Intervention groups

1

Description
Intervention group: 42 preterm infants with a gestational age of less than 32 weeks and a weight of between 1,000-1,500 g and matched with clinical inclusion criteria for the study randomly assigned and recived one drop per kilogram of body weight of probiotic(Pedilact droplet of Zist takhmir Company) solution twice daily.
Category
Prevention

2

Description
Control group: 42 preterm infants with a gestational age of less than 32 weeks and a weight of between 1,000-1,500 g and matched with clinical inclusion criteria for the study randomly assigned and recived one drop per kilogram of body weight of Dish water twice daily.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Motahhari Hospital
Full name of responsible person
Dr Kamran Dehghan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr Iraj Mohebbi
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Urmia university of medical sciences-Resalat Blvd-Emergency Alley. Urmia Vest Azarbaijan Iran, Islamic Republic Of
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mohebbi_iraj@yahoo.co.uk
Web page address
http://faculty.umsu.ac.ir/Site/CV.aspx?STID=15&Ln=fa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia University of Medical Sciences
Proportion provided by this source
100

Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Siamack Karimi Heydarabad
Position
Resident
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data forms potentially can be shared after unidentifiable individuals.
When the data will become available and for how long
The access period start one year after the print results
To whom data/document is available
Only for researchers working in academic and academic institutions
Under which criteria data/document could be used
In the case of scientific authentication, information will be provided to them
From where data/document is obtainable
Dr. Siamak Karimi’s Email(Pediatric Resident)

siamack.karimi@gmail.com

What processes are involved for a request to access data/document

Upon receipt of the email, the request will be contacted by the applicant

Comments