

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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, randomized 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, received 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 malformations 3- Genetic anomalies (e.g Trisomy 21 or other trisomies) 4- Considered likely to die within 72 hours of birth 5- Death before minimal enteral 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 receive 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)

Phone

+98 44 3365 4154

Email address

dehghan.k@umsu.ac.ir

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 $\alpha = 0.05$ 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

Urmia

Province

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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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Motahhari hospital, Kashani Av Urmia Vest Azarbaijan Iran, Islamic Republic Of

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<http://www.motahhari.umsu.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr Iraj Mohebbi

Street address

Urmia university of medical sciences-Resalat Blvd-Emergency Alley. Urmia Vest Azarbaijan Iran, Islamic Republic Of

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<http://faculty.umsu.ac.ir/Site/CV.aspx?STID=15&Ln=f a>

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

Medical doctor

Other areas of specialty/work

Pediatrics

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Dr Kamran Dehghan

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Neonatologist

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Postal code

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Phone**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/documentAll 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 availableOnly 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