Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

The effect of oral probiotics in prevention of necrotizing enterocolitis in premature neonates.

Protocol summary

Summary

The aim of this study is to determine the effect of oral probiotics in prevention of necrotizing enterocolitis in premature neonates. This study is a double blind randomized controlled trial. Fifty premature neonates with gestational age of less than 36 weeks and birth weight of 1000-2500 gr who need NICU care will enroll in the study. Neonates with gasterointestinal obstruction, congenital heart diseases, omphalocele, gasterochesia, asphyxia (grades II or III) and maternal addiction will be excluded from the study. Neonates will be randomly allocated in two groups: Treatment and placebo. The treatment group, when milk volume reaches to 5 cc/kg/day, will receive 1 drop/kg of oral probiotic (diluted to 0.5 ml with normal saline) each 12 hours. The placebo group will receive 0.5 ml normal saline each 12 hours. The drug and placebo which are prepared in similar syringes will be administered by a nurse, trained before the study. NEC and its severity will be diagnosed according to the following criteria: Stage I(suspected NEC): apnea, lethargy, hematochezia, abdominal distention, temperature instability, gastric retention, without radiographic findings. Stage II (documented NEC): signs of stage I plus thrombocytopenia with or without mild metabolic acidosis, abdominal tenderness, pneumatosis or gas in portal vein. Stage III (advanced NEC): signs of stage II plus hypotension, bradycardia, severe apnea, respiratory and metabolic acidosis, DIC, abdominal tenderness, neutropenia, pneumoperitonitis. After data collection, necrotizing enterocolitis, time to full enteral feeding and duration of hospitalization were compared between two groups .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014022716574N3**

Registration date: **2014-05-24, 1393/03/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-24, 1393/03/03

Registrant information

Name

Fatemeh Naghibifard

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1726 2871

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2013-07-23, 1392/05/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral probiotics in prevention of necrotizing enterocolitis in premature neonates.

Public title

The effect of probiotics in prevention of necrotizing

enterocolitis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Neonates with gestational age <36 weeks; Birth weight 1000-2500 grams and admitted in NICU ward of the Shahid Sadughi hospital; Yazd
Exclusion criteria: Neonates with obstruction of gasterointestinal; Congenital heart disease; Omphalocele; Gasterochesia; Asphyxia (grade II,III)and Addiction of mother.

Age

From **1 day** old to **3 months** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Shahid Sadoughi Univercity of Medical Sciences

Street address

Bahonar Square

City

Yazd

Postal code

8915845354

Approval date

2014-03-08, 1392/12/17

Ethics committee reference number

257428/1/17

Health conditions studied

1

Description of health condition studied

Necrotizing enterocolitis

ICD-10 code

P77

ICD-10 code description

Necrotizing enterocolitis of fetus and newborn

Primary outcomes

1

Description

Necrotizing enterocolitis

Timepoint

During intervention

Method of measurement

Bell staging criteria

Secondary outcomes

1

Description

When full enteral feeding is reached

Timepoint

During intervention

Method of measurement

Per day

2

Description

Weight of neonate at the time of discharged

Timepoint

When the neonate is discharged

Method of measurement

With scale(seca)

3

Description

During hospitalization

Timepoint

When the neonate is discharged

Method of measurement

Per day

4

Description

Mortality

Timepoint

During intervention

Method of measurement

Per person

Intervention groups

1

Description

Intervention group: When volume of feeding reaches to 5cc/kg/day, 1 drop/kg of oral probiotics drop (Pedilact,

Sepehr Pharmaceutics, Iran) diluted with normal saline to 0.5cc will be administered each 12 hours.

Category

Prevention

2

Description

Control group: 0.5 cc of normal saline (Samen Pharmaceutics, Iran) will be administered each 12 hours when volume feeding reaches to 5 cc/kg/day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital

Full name of responsible person

Fateme Naghibifard

Street address

Shahid Sadoughi Hospital, Shahid Ghandi Avenue, Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Fateme Ezodini

Street address

Bahonar Square, Yazd

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research, Shahid Sadoughi University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Sadoughi Hospital

Full name of responsible person

Fateme Naghibifard

Position

Pediatric resident

Other areas of specialty/work

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty