

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Probiotic effect on prevention of feeding intolerance in neonates under 1500 grams

Protocol summary

Summary

The aim of this study is to determine the effect of oral probiotic on prevention of feeding intolerance in neonates under 1500 grams. This study is a double blind randomized clinical trial. sixty neonates with birth weight of less than 1500 grams who need NICU care will enroll in the study. Neonates will be randomly allocated in two groups: Treatment and control. Neonates with gastrointestinal tract obstruction; congenital heart disease; congenital anomalies and death in first 72 hour of life and if mother receiving probiotic supplement and formula fed neonates will be excluded from the study. Neonates with inclusion criteria for study divided by two group of treatment and control by discharging white and yellow cards from closed bag. In treatment group, when feeding volume reaches to 5cc/kg/day, will receive 4 drop/day in neonates with weight of 1000-1500 grams and 2 drop/day in neonates with weight of less than 1000 grams and will add to breast milk and will order Q12hour and will continue until full feeding of neonates(120-160cc/kg/day). Routine treatment of background disease will accomplish in control group. Milk will increase 20-30 cc/kg day in every day. Feeding intolerance and NEC and their severity will be diagnosed according following criteria: stage one (suspected NEC): signs and symptoms consist of apnea, letargy, hematochezia, abdominal distention, temperature instability, gastric retention, without radiographic findings. stage two(documented NEC): signs of stage one plus thrombocytopenia with or without metabolic and respiratory acidosis, DIC, abdominal tenderness and existence of pneumatosis or gas in portal vein. stage three(advanced NEC): signs of stage two plus hypotension, bradycardia, sever apnea, respiratory and metabolic acidosis, DIC, clear abdominal tenderness, neutropenia and pneumoperitonitis. After data collection, abdominal distention, vomiting and gastric retention and time to enteral feeding and duration of hospitalization and death will compare between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111925125N1**

Registration date: **2016-01-18, 1394/10/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-18, 1394/10/28

Registrant information

Name

Alireza Yahyaee Shahandashti

Name of organization / entity

Chidrn's Hospital Amirkola

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research Technology Affairs, Babol University of Medical Sciences

Expected recruitment start date

2015-12-08, 1394/09/17

Expected recruitment end date

2016-04-22, 1395/02/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Probiotic effect on prevention of feeding intolerance in neonates under 1500 grams

Public title

Probiotic effect on prevention of feeding intolerance

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Neonates with birth weight < 1500 grams and admitted in NICU ward of Rohani hospital; Babol. Exclusion criteria: Neonates with obstruction of gastrointestinal tract; Congenital heart disease; Death in first 72 hour of life and if mother receiving probiotic supplement and Formula fed neonates.

Age

From 1 month old to 1 month old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafroz Street, Babol. Mazandaran, IR Iran.

City

Babol

Postal code

4717647745

Approval date

2015-12-06, 1394/09/15

Ethics committee reference number

30/6446/ب/ز

2

Ethics committee

Name of ethics committee

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City

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Postal code

4717647745

Approval date

2015-12-06, 1394/09/15

Ethics committee reference number

306446.ب.ز

Health conditions studied

1

Description of health condition studied

Feeding intolerance

ICD-10 code

11

ICD-10 code description

Diseases of the Digestive system

Primary outcomes

1

Description

Feeding intolerance

Timepoint

During intervention

Method of measurement

During intervention

Secondary outcomes

1

Description

When full enteral feeding is reached

Timepoint

During intervention

Method of measurement

During intervention

2

Description

When birth weight is reached

Timepoint

During intervention

Method of measurement

During intervention

Intervention groups

1

Description

Intervention group: When volume of feeding of neonate reaches to 5cc/kg/day, 2drop/12 h in neonates with birth weight of 1000-1500 grams and 1drop/12h in neonates with birth weight of less than 1000 grams of oral probiotics drop (Pedilact)Zist takhmir Pharmaceuticals production will be administered until enteral fullfeeding time.

Category

Treatment - Drugs

2

Description

Controle group: Background disease treatment will accomplish and plasebo willnot administered.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rohani Hospital, Babol

Full name of responsible person

Alireza Yahyaee SHahandashti

Street address

Rohani Hospital, Keshavarz Street, Babol

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Babol University of Medical Sciences, Vice-Chancellor for reasearch Technology Affairs

Street address

Babol University of Medical Sciences, Ganjafroz Street, Babol. Mazandaran. IR Iran

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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

Babol 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

Amirkola Children's Hospital

Full name of responsible person

Alireza Yahyaee Shahandashti

Position

Neonatal Assistant

Other areas of specialty/work

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Position

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Other areas of specialty/work

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Web page address

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