

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of probiotics in premature newborn infants in the NICU and neonatal wards at Vali-Asr hospital year 1391

Protocol summary

Summary

The aim of the study was to evaluate the effect of probiotics in premature newborn that Inclusion criteria: All infants below 2000 grams and over 750 grams and infants less than 37 weeks . Exclusion criteria: infants under 2000 grams, 750 grams and above, family immunodeficiency, congenital heart disease. After a group of stable vital signs and starting with minimal entral feeding to 1-8 / 0 g per day in divided doses with each feeding in the first 10 days after birth Sasho Protexin Powder 1 gram daily for 7 days or more is prescribed.Around the abdomen, bowel sounds, gastric lavage, fecal occult blood and full of feces daily, weigh daily, weekly head circumference, height and time to milk at 120-150 cc / kg / day,NEC symptoms such as drowsiness, lethargy, biliary lavage, lavage more than 50% milk three hours, increased abdominal girth of more than 2cm and stability than the previous feeding period of 6-4 hours and a clear blood in the stool as NEC onset of symptoms and NEC clinical and radiographic signs of disease are reviewed. Another group in the same group are considered as two sides Blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210209568N3**

Registration date: **2013-12-20, 1392/09/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-12-20, 1392/09/29

Registrant information

Name

Golnaz Rezaeizadeh

Name of organization / entity

Maternal Fetal Neonatal Research Center,Tehran
University of Medical Sciences, Tehran, Iran

Country

Iran (Islamic Republic of)

Phone

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Email address

mfnhrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotics in premature newborn infants in the NICU and neonatal wards at Vali-Asr hospital year 1391

Public title

The effect of probiotics in premature newborn

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: All infants below 2000 grams and over 750 grams and infants less than 37 weeks Exclusion criteria: infants under 2000 grams, 750 grams and above, family immunodeficiency, congenital heart disease

Age

To 37 years 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

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Ethics committee of Tehran University of Medical Sciences, 6th floor of Tehran University of Medical Sciences, Ghods St., Keshavarz blv, Tehran, Iran

City

Tehran

Postal code

1419733141

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

91-03-91-19454-96454-96819

Health conditions studied

1

Description of health condition studied

Weight Gain

ICD-10 code

p92.9

ICD-10 code description

feeding problem of newborn

Primary outcomes

1

Description

feeding

Timepoint

under observation

Method of measurement

observation

Secondary outcomes

1

Description

NEC

Timepoint

Under Observation

Method of measurement

Observation-clinical exam

Intervention groups

1

Description

Intervention group: using Proxtrin powder, which is a probiotic substance, 1 gram sachet for 7 days in the first 10 days after birth

Category

Lifestyle

2

Description

Control group: no use of 1 gram powder sachet proxtrin the first 10 days of birth

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

samane sedghi

Street address

Vaiasr hospital, Imam Khomeini Hospital complex, Keshavarz blv, 14914, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Maternal Fetal Neonatal Research Center, Tehran University of Medical Sciences

Full name of responsible person

Mamak Shariat

Street addressVaiastr hospital,Imam Khomeini Hospital complexex,
Keshavarz blv, Tehran, Iran**City**

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceMaternal Fetal Neonatal Research Center,Tehran
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**Maternal Fetal Neonatal Research Center,Tehran
University of Medical Sciences, Tehran, Iran**Full name of responsible person**

samane sedghi

Position

researcher/MD

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Ehahe Amini

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professor/neonatologist

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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*