

# 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

+98 21 6119 2357

##### 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 address**Vaiastr 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 source**Maternal 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

**Other areas of specialty/work****Street address**Vaiastr hospital,Imam Khomeini Hospital complexex,  
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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**Maternal Fetal Neonatarch Center,Tehran University  
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Ehahe Amini

**Position**

professor/neonatologist

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University of Medical Sciences**Full name of responsible person**

Samane Sedghi

**Position**

researcher/MD

**Other areas of specialty/work****Street address**Vaiastr hospital,Imam Khomeini Hospital complexex,  
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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*