

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Effect of probiotic in prevention of Necrotizing Enterocolitis in preterm infants in Hafez hospital

Protocol summary

Summary

The aim of this study was to evaluate the effect of probiotics in preventing necrotizing enterocolitis in preterm infants under 1500 grams, Including criteria, stable neonate that began feeding. Population of study, hospitalize infant under 1500gr in Hafez Hospital that 83 cases and 83 control were considered. After starting probiotict drop they follow clinically exam daily.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072618591N1**

Registration date: **2014-09-17, 1393/06/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-17, 1393/06/26

Registrant information

Name

Seyed Mostajab Razavi

Name of organization / entity

Shiraz University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 71 3612 5479

Email address

razavimo@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University Of Medical Science

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotic in prevention of Necrotizing Enterocolitis in preterm infants in Hafez hospital

Public title

Effect of probiotic in prevention of Necrotizing Enterocolitis in preterm infants in Hafez hospital

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: premature neonate with 1500 gr and below that stable and tolerate (10cc/kg/day) formula or breast milk. exclusion criteria: decline to participate; sever congenital anomaly; death

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **166**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University Of Medical Science

Street address

Building of Shiraz University Of Medical Science, Zand street, Shiraz

City

Shiraz

Postal code**Approval date**

2014-07-14, 1393/04/23

Ethics committee reference number

CT-P-9367-6757

Health conditions studied**1****Description of health condition studied**

Necrotizing enterocolitis

ICD-10 code

A09.0

ICD-10 code description

Other and unspecified gastroenteritis and colitis of infectious origin

Primary outcomes**1****Description**

sign and symptom of NEC

Timepoint

daily examination

Method of measurement

clinical evaluation

Secondary outcomes**1****Description**

feeding tolerant

Timepoint

daily examination

Method of measurement

clinical follow up

Intervention groups**1****Description**

Intervention group: add probiotics (Probiotic drops Pedilact Manufacturing zist takhmir) milk at the rate of 0/1cc/kg/day until hospital

Category

Treatment - Drugs

2**Description**

control group: The control group was used as control and did not receive drug

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hafez Hosaital

Full name of responsible person

Dr. Fazel Makvandi

Street address

Hafez Hospital, chamran street, Shiraz

City

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Dean Of Research Of Shiraz University Of Medical Science

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

7th Floor dean of research, Building of University Of Medical Science, Zand street, Shiraz

City

Shiraz

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

Yes

Title of funding source

Dean Of Research Of Shiraz University Of Medical Science

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**Neonatology research center, Shiraz University Of
Medical Science**Full name of responsible person**

Dr.Shahnaz Pourarian

Position

Professor of Neonatology

Other areas of specialty/work**Street address**Neonatology research center, Neonatal department,
Namazi Hospital, Shiraz**City**

Shiraz

Postal code**Phone**

+98 71 3612 5479

Fax**Email**

porarish@sums.ac.ir

Web page address**Postal code****Phone**

+98 71 3612 5479

Fax**Email**

razavimo@sums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University Of Medical Science

Full name of responsible person

Dr.Fazel Makvandi

Position

Flowship of neonatal

Other areas of specialty/work**Street address**Neonatal Research Center, Neonatal Department,
Nemazee Hospital, Zand Street, Shiraz**City**

Shiraz

Postal code**Phone**

+98 71 3612 5479

Fax**Email**

fazelmakvandi21@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**Neonatology Research Center, Shiraz University Of
Medical Science**Full name of responsible person**

Dr.Seyed Mostajab Razavi

Position

Associated Professor of Neonatology

Other areas of specialty/work**Street address**Neonatal Research Center, Neonatal Department,
Namazi Hospital, Zand Street, Shiraz**City**

Shiraz

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*