

# 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 gastrointestinal 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

###### Email address

dr\_naghibifard@ssu.ac.ir

##### 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 Sadoughi hospital; Yazd

Exclusion criteria: Neonates with obstruction of gastrointestinal; Congenital heart disease; Omphalocele; Gastrochisis; 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 University 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 Pharmaceuticals, 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 Pharmaceuticals, 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**

**Street address**

Shahid Sadoughi Hospital, Shahid Ghandi Avenue, Yazd

**City**

Yazd

**Postal code**

8916886938

**Phone**

+98 35 1822 4000

**Fax**

+98 35 1822 4100

**Email**

Naghibifard\_128@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Dr.Mahmood Noorishadkam

**Position**

Neonatologist

**Other areas of specialty/work**

**Street address**

Bahonar Square, Yazd

**City**

Yazd

**Postal code**

8916886938

**Phone**

+98 35 1822 4000

**Fax**

+98 35 1822 4100

**Email**

Noorishadkam@ssu.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Sadoughi Hospital

**Full name of responsible person**

Fateme Naghibifard

**Position**

Pediatric resident

**Other areas of specialty/work**

**Street address**

Shahid Sadoughi Hospital, Shahid Ghandi Avenue,

Yazd  
**City**  
Yazd  
**Postal code**  
8916886938  
**Phone**  
+98 35 1822 4000  
**Fax**  
+98 35 1822 4100  
**Email**  
Naghifard\_128@yahoo.com  
**Web page address**  
www.ssu.ac.ir

## 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*