

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### **lactulose effectiveness on incidence of suspected NEC in VLBW infants in Al\_zahra and shahid baheshti hospitals in Isfahan**

#### **Protocol summary**

##### **Summary**

Colonization of infants' sterile intestine starts immediately after birth with harmful and beneficial bacteria. This first colonization changes rapidly under effect of infant diet. Flora microbe in term and preterm infant differs from each other. Beneficial bacteria in preterm infants is less than in term but rather the amount of potentially pathogenic bac.in preterm infant is more than term. Furthermore prescription of antibiotics and admission in NICU increased risk of neonatal infections. Though most serious infections in preterm infants due to CONS from external sources but in many cases serious infections can be developed in results of internal source particularly harmful bacteria of GI.it has been shown that adding lactulose increase flora bifidogenic and reduce pathogenic flora and increase short chain fatty acids. Short chain fatty acids improve intestinal integrity and reduce growth of pathogens and regulate intestinal movements. Based on the above we went on to investigate the effect of adding lactulose on NEC in preterm infant <1500 gr.

#### **General information**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT2015020110026N6**

Registration date: **2015-03-06, 1393/12/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### **Registration date**

2015-03-06, 1393/12/15

##### **Registrant information**

##### **Name**

Amir mohammad Armanian

##### **Name of organization / entity**

Isfahan University of Medical Sciences

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 31 1235 5059

##### **Email address**

armanian@med.mui.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

Isfahan University of Medical Sciences, Isfahan, Iran

##### **Expected recruitment start date**

2014-01-01, 1392/10/11

##### **Expected recruitment end date**

2015-01-20, 1393/10/30

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

##### **Trial completion date**

empty

##### **Scientific title**

lactulose effectiveness on incidence of suspected NEC in VLBW infants in Al\_zahra and shahid baheshti hospitals in Isfahan

##### **Public title**

The effect of Lactolose on premature infants

##### **Purpose**

Prevention

##### **Inclusion/Exclusion criteria**

Inclusion criteria: prematurity; birth weight equal and lower than 1500 gr; at the time of beginning milk.

Exclusion criteria: major congenital anomalies; asphyxia; GI anomalies; congenital cyanotic heart disease.

##### **Age**

To 30 days old

##### **Gender**

Both

**Phase**  
N/A

**Groups that have been masked**  
No information

**Sample size**  
Target sample size: 50

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan University of Medical Sciences

##### Street address

Faculty of Medicine, Isfahan University of Medical Sciences, Hezar Jerib st.

##### City

Isfahan

##### Postal code

#### Approval date

2013-06-27, 1392/04/06

#### Ethics committee reference number

392273

## Health conditions studied

### 1

#### Description of health condition studied

NEC

#### ICD-10 code

P77

#### ICD-10 code description

Necrotizing enterocolitis of fetus and newborn

## Primary outcomes

### 1

#### Description

GI microbial changes

#### Timepoint

30 days

#### Method of measurement

Stool exam

### 2

#### Description

NEC

#### Timepoint

30 days

#### Method of measurement

Patient examination and observation

## Secondary outcomes

### 1

#### Description

Hospital stay

#### Timepoint

30 days

#### Method of measurement

Daily recorded sheets

### 2

#### Description

Death

#### Timepoint

During hospital stay

#### Method of measurement

Daily recorded sheets

### 3

#### Description

Being NPO

#### Timepoint

30 days

#### Method of measurement

Daily recorded sheets

### 4

#### Description

Milk intolerance

#### Timepoint

30 days

#### Method of measurement

Daily recorded sheets

### 5

#### Description

Time of becoming full volume

#### Timepoint

30 days

#### Method of measurement

Daily recorded sheets

## Intervention groups

**1**

**Description**

In the lactulose given group after consideration the inclusion and exclusion criteria for premature infant <1500gr that their milk begin lactulose 1%added and it continued on till the milk volume 150 cc/kg per day

**Category**

Treatment - Drugs

**2**

**Description**

In the control group after consideration the inclusion and exclusion criteria for premature infant<1500 gr that their milk begin water injectin added and it cntinues to till the milk volume to 150 cc/kg per day .

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

NICU at Alzahra and Shahid Beheshti hospitals in Isfahan IRAN

**Full name of responsible person**

Dr. Amir Mohammad Armanian

**Street address**

Number 133, Shahid Ansari alley, Saeb street, Isfahan, Iran

**City**

Isfahan

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr. Ebrahim Esfandiari

**Street address**

Faculty of Medicine, Isfahan University of Medical Sciences, Hezar Jerib st.

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Isfahan 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**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr. Elahe Shirani

**Position**

Resident of pediatrics

**Other areas of specialty/work**

**Street address**

Dpartment of pediatrics, Isfahan University of Medical Sciences

**City**

Isfahan

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**Phone**

+98 31 3335 3034

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shirani\_elahe@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr. Amir Mohammad Armanian

**Position**

Neonatologist

**Other areas of specialty/work**

**Street address**

Number 133, Shahid Ansari alley, Saeb street, Isfahan, Iran

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8184757851

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**Contact**

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr. Amir Mohammad Armanian

**Position**

Assistant professor of neonatology

**Other areas of specialty/work****Street address**

Number 133, Shahid Ansari alley, Saeb street,  
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**Postal code****Phone**

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**Fax****Email**

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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*