

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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

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Email address

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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

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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

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Person responsible for updating data

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**

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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