Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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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.

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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

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Position
Neonatologist

Other areas of specialty/work

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Assistant professor of neonatology
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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