Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of early administration of oropharyngeal colostrum on immune status and common morbidities of premature infants with gestational age Less or equal 30 weeks and birth body weight Less or equal 1500 gram

Protocol summary

Study aim

Effect of early administration of oropharyngeal colostrum on immune status and common morbidities of premature infants

Design

Clinical trial with control group, with parallel groups, double-blind

Settings and conduct

60 children will be selected from Al-Zahra and Beheshti hospitals. The milk room nurse knows which baby should receive colostrum or distilled water. She puts the babys' nutrition with a large label containing the baby's name in the refrigerator and prescribes the specified content, every 3 hours, through the oropharynx for 72 hours. Oropharyngeal administration also begins as soon as possible during the first 36 hours after birth. A urine sample is taken from the baby before the first dose. The babysitter and data analyzer are blinded.

Participants/Inclusion and exclusion criteria

Inclusion:Infants less than or equal to 30 weeks old and weighing less than or equal to 1500 g, Absence of major congenital malformations, Apgar higher than 4 in the fifth minute of birth, Exclusion:Lack of colostrum needed by infant mother, Diagnosis of early sepsis with positive blood culture, Need to continue receiving aminoglycoside after the first 96 hours of birth, Mother's HIV infection, History of maternal chorio amnionitis.

Intervention groups

Thirty infants in the intervention group received their maternal colostrum every 3 hours for 72 hour,the correct metod of breast feeding and the properties of colostrum were explained to mothers in one hour session. Thirty infant in the control group received ampoules containing 5 cc distilled water prepared by Shahid Ghazi Pharmaceutical Company every 3 hours for 72 hours. oropharyngeal administration was started as soon as possible during the first 36 hours after birth.

Main outcome variables

Urinary IgA Concentration, Duration of Complete Intestinal Nutrition, Prevalence of Necrotizing Enterocolitis, Hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171230038142N19**
Registration date: **2020-08-16, 1399/05/26**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-16, 1399/05/26**
Update count: **0**

Registration date

2020-08-16, 1399/05/26

Registrant information

Name

Khosro Tavakol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 9134

Email address

tavakol@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-05, 1398/12/15

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of early administration of oropharyngeal colostrum on immune status and common morbidities of premature infants with gestational age Less or equal 30 weeks and birth body weight Less or equal 1500 gram

Public title

Effect of early administration of oropharyngeal colostrum on immune status and common morbidities of premature infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Infants less than or equal to 30 weeks old and weighing less than or equal to 1500 g Absence of major congenital malformations Apgar higher than 4 in the fifth minute of birth

Exclusion criteria:

Unable to provide colostrum by the mother, to the extent required for study Diagnosis of early sepsis with positive blood culture Urinary Tract Infection Need to continue receiving aminoglycoside after the first 96 hours of birth Maternal HIV infection History of maternal chorio amnionitis

Age

From **1 day** old to **1 day** old

Gender

Both

Phase

2-3

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

First, all mothers were asked to breastfeed as soon as possible and put it in a special sterile container. The nurse, who is familiar with the process, then takes the dishes from the mothers. The nurse, who is not present during the rest of the research, prepares colostrum syringes and distilled water, and each insulin syringe containing colostrum or distilled water is stamped with a large label that says the date of aggregation or distilled water and the baby's name. So that the content inside it is not clear and the neonatal nurse (clinical caregiver) does not understand and feeds each baby based on the syringe on which the baby's name is, and therefore is blinded in the process. Data analyzer is not aware of how to do the job.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jereyb Ave.

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2020-02-01, 1398/11/12

Ethics committee reference number

IR.MUI.MED.REC.1398.559

Health conditions studied

1

Description of health condition studied

Premature Infants

ICD-10 code

O42.019

ICD-10 code description

Preterm premature rupture of membranes, onset of labor within 24 hours of rupture, unspecified trimester

Primary outcomes

1

Description

Urinary IgA Concentration

Timepoint

Before the intervention, eighth day of birth, 15th day of birth

Method of measurement

Measurement of IgA concentration in urine samples using Turbidometry method

2

Description

The prevalence of necrotizing enterocolitis

Timepoint
During hospitalization
Method of measurement
Counting cases

3

Description
The prevalence of mortality
Timepoint
During hospitalization
Method of measurement
death count

4

Description
Duration of complete intestinal nutrition
Timepoint
During hospitalization
Method of measurement
Counting the days

5

Description
Duration of hospitalization
Timepoint
Duration of hospitalization
Method of measurement
Counting the days

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For infants in this group, a syringe containing colostrum taken from the milk of infants' own mothers (0.2 ml) is oropharyngeally administered on the left and right sides of their mouth mucosa slowly for at least 2 minutes every 3 hours. The mentioned procedure continues for 72 hours from the beginning of the intervention. Before each appointment, the nurse will make sure that no secretion requiring suction is in the infants' mouth and nose.
Category
Treatment - Drugs

2

Description
Control group: For infants in this group, a syringe containing distilled water (0.2 ml) is oropharyngeally administered on the left and right sides of their mouth mucosa slowly for at least 2 minutes every 3 hours. The mentioned procedure continues for 72 hours from the beginning of the intervention. Before each appointment, the nurse will make sure that no secretion requiring suction is in the infants' mouth and nose.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital of Isfahan
Full name of responsible person
Majid Mohammadi Zadeh
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Esfahan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Azadeh Jafari

Position
Consultant

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The information is shared two years after the results are published.

When the data will become available and for how long

The information is shared two years after the results are published.

To whom data/document is available

Doctors and pediatricians

Under which criteria data/document could be used

Comparison of the present method with another method or treatment

From where data/document is obtainable

Send mohammadizadehm_z@yahoo.com an email

What processes are involved for a request to access data/document

Send mohammadizadehm_z@yahoo.com an email

Comments