Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Investigating the effect of Oropharyngeal colostrum in the prevention of late-onset sepsis in preterm infants admitted to neonatal intensive care unit by extraoral massage method

Protocol summary

Study aim

Determining the effect of colostrum orally-pharyngeal in the prevention of late-onset sepsis in premature infants admitted to the neonatal intensive care unit by extraoral massage method

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 70 babies, Random Allocation Software was used for randomization.

Settings and conduct

To conduct the study, the researcher referred to the special care department of Ayat Rohani Hospital in Babol and selected the eligible premature babies into two groups of 35. In the control group, 0.2 ml of mother's colostrum was administered as a mouthwash every 3 hours, and in the intervention group, 0.4 ml of mother's colostrum was administered orally every 3 hours for 7 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria include premature infants with a gestational age between 28 and 32 weeks, premature infants without congenital abnormalities (gastrointestinal disorders) or genetic syndromes, premature infants without mechanical ventilation, the infant being NPO, not having premature sepsis or not having sepsis risk factors. Premature, the mother's lack of active viral infections during pregnancy and childbirth; Exclusion criteria include the condition of the infant not being stable during the intervention more than twice (loss of saturation, bradycardia,...), parents' refusal to continue the research project or death of infants before 7 days, infants needing urgent surgery.

Intervention groups

In the control group, 0.2 ml of mother's ooze was poured as a mouthwash every 3 hours, and in the intervention group, 0.4 ml of ooze was applied (by oral-pharyngeal method) on the surface of the gums (buccal cavities), cheek, palate and the surface of the tongue. It is poured for 3 hours and each cheek is massaged from the outside of the mouth using the index finger.

Main outcome variables

late-onset sepsis

General information

Reason for update

Acronym

OPT,OAC,C-OIT

IRCT registration information

IRCT registration number: **IRCT20230312057698N1**
Registration date: **2023-03-29, 1402/01/09**
Registration timing: **prospective**

Last update: **2023-03-29, 1402/01/09**
Update count: **0**

Registration date

2023-03-29, 1402/01/09

Registrant information

Name

Neda Behroj

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-09, 1402/01/20

Expected recruitment end date

2024-04-08, 1403/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Oropharyngeal colostrum in the prevention of late-onset sepsis in preterm infants admitted to neonatal intensive care unit by extraoral massage method

Public title

Investigating the effect of Oropharyngeal colostrum in the prevention of late-onset sepsis in preterm infants admitted to neonatal intensive care unit by extraoral massage method

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Premature infants with a gestational age between 28 and 32 Premature infants without congenital abnormalities (digestive disorders) or genetic syndromes Premature infants without mechanical ventilation infant being NPO Not having early sepsis or not having early sepsis risk factors The mother's absence of active viral infections during pregnancy and childbirth

Exclusion criteria:

The infant's condition is not stable during the intervention more than twice (loss of saturation, bradycardia,...) Parents withdraw from continuing the research project or infants die before 7 days infants need urgent surgery

Age

From **1 day** old to **2 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a parallel randomized controlled trial (parallel randomized controlled trial) considering that not all babies are included in the study at the same time and researchers cannot predict in advance which group each baby who is included in the study will belong to, for allocation Block randomization will be used to assign each baby to one of the two groups. In order to hide the random allocation, the codes created by the software will be placed in opaque envelopes so that it is not clear which group the next person will be assigned to. In order to hide the random allocation, the codes created by the software will be placed in opaque envelopes so that it is not clear which group the next person will be assigned to. In this study, the participating infants will be assigned to one of two control and intervention groups according to the random block division protocol (produced by Random Allocation Software) with a ratio of 1:1 and in blocks of 6, so that the researcher It cannot predict which intervention group the next person is placed in. The codes will be placed in the opaque envelopes, and with the entry of each new person, the envelope will be opened and the person's belonging to the relevant group will be determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

Regarding the blinding method, this design is double-blind. In this study, the researcher and the nurses of the executive team are informed about the goals of the project and the groups, but the baby's parents, the evaluator (neonatal doctor) and the analyst (the person who performs the statistical analysis) are not aware of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Mazandaran, Babol, Ganj Afrooz Road, Babol University of Medical Sciences - Faculty of Nursing and Midwifery - Department of Nursing

City

Babol

Province

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Postal code

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Approval date

2023-03-11, 1401/12/20

Ethics committee reference number

IR.MUBABOL.REC.1401.199

Health conditions studied

1

Description of health condition studied

late-onset sepsis

ICD-10 code

P36

ICD-10 code description

Bacterial sepsis of newborn

Primary outcomes

1

Description

late-onset sepsis

Timepoint

72 hours after birth

Method of measurement

In order to distinguish clinical sepsis from other differential diagnoses in the intensive care unit of newborns, two factors CRP (C-reactive protein) and PCT (procalcitonin) are checked for suspected babies.Clinical sepsis by examining 6 criteria that include general appearance symptoms (temperature instability, paleness, skin reticulation or motilization, jaundice, bruising, petechiae) and nervous system symptoms (lethargy or irritability, hypertonia or hypotonia, loud crying) loud, trembling, restlessness) and symptoms of the cardiovascular system (tachycardia or bradycardia, hypotension, cyanosis) and symptoms of the respiratory system (apnea or tachypnea, decrease in blood oxygen saturation, hearing the sound of a baby moaning or grunting, drawn in chest muscles or retraction) and digestive system symptoms (abdominal distention, vomiting, food intolerance, diarrhea) and urinary reproductive system symptoms (decrease in urinary output or oliguria)] are determined.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, 0.4 ml (4 units) of mother's colostrum was drawn into a 1 ml syringe (insulin syringe) and 0.2 ml (2 units) on each side of the mouth on the gum surface (buccal cavities).), cheek, palate, and tongue surface every 3 hours for 7 days, and each cheek is massaged from the outside of the mouth for at least 10 seconds using the index finger.

Category

Prevention

2

Description

Control group: In the control group, routine oral care of the neonatal intensive care unit will be performed. In this group, mother's colostrum in the amount of 0.2 ml of colostrum is poured into the baby's mouth as a mouthwash every 3 hours for 7 days and cleaned with a swab.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mazandaran, Babol,Ayatollah Rouhani Hospital

Full name of responsible person

Dr. Asghar Molazadeh

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Sponsors / Funding sources

1

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Full name of responsible person

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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

Babol 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
Babol University of Medical Sciences
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Nursing master's student in neonatal special care
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable