Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

To assess the efficacy of oropharyngeal colostrum therapy on short outcome among preterm neonates

Protocol summary

Study aim

To assess the efficacy of oropharyngeal colostrum therapy on short outcome among preterm neonates

Design

This clinical trial study is designed as a double-blind, randomized placebo control group, and 126 preterm infants divided into 2 Groups are identified as groups A and B. The performer and the collector are not aware of the actual names of the group's The cards shuffling method is used for refinement.

Settings and conduct

To hide the random allocation process, the order of interventions will be written on 126 cards and each card will be placed in an envelope.

Participants/Inclusion and exclusion criteria

Inclusion criteria for premature infants under 32 weeks or weighing less than 1500 grams are hospitalized in the intensive care unit of Fatemieh Hospital in Hamadan. The exclusion criteria are genetic and chromosomal disorders, HIV-positive mothers, and drug-addicted mothers—any case where there is a contraindication for milk feeding for the baby.

Intervention groups

63 infants received 0.2 ccs of their mother's colostrum through the oropharynx every 6 hours to 3 days from birth to the first 72 hours of birth. The other 63 infants were placebo and received 0.2 ccs of distilled water. And due to the apparent difference between distilled water and colostrum, the syringes are covered with white paper glue and the appearance of colostrum or distilled water is not seen.

Main outcome variables

Short-term prognosis of mortality and incidence of necrotizing enterocolitis and ventilator-associated pneumonia and the incidence of cerebral hemorrhage and the incidence of definite and clinical infections and the duration of hospitalization and the duration of complete oral nutrition in these infants and the rate of neonatal retinopathies Premature babies who need laser surgery are examined. The studied neonates will be monitored for a short period of up to one month.

General information

Reason for update

In the method, the mother's colostrum was given oropharyngeal every six hours for three days, starting from birth to the first 72 hours of the baby's birth.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210607051507N2**
Registration date: **2021-09-25, 1400/07/03**
Registration timing: **prospective**

Last update: **2024-02-23, 1402/12/04**
Update count: **1**

Registration date

2021-09-25, 1400/07/03

Registrant information

Name
Ameneh Lamsehchi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 6656 1315
Email address
lamsehchila@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-02, 1400/07/10

Expected recruitment end date

2022-03-01, 1400/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To assess the efficacy of oropharyngeal colostrum therapy on short outcome among preterm neonates

Public title

The effect of colostrum on the short outcome of premature infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Premature infants under 32 weeks of gestation Or below 1500 grams

Exclusion criteria:

Genetic and chromosomal abnormalities, HIV-positive mother, drug-addicted mother Any case where there is a limitation on milk usage for the baby

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

Our sample size is 126, which is done by the cards or envelopes shuffling method. In this method, a number of cards selected by the researcher as group A and the same number of cards for group B are considered. This card will be returned to the other cards after leaving.

Blinding (investigator's opinion)

Double blinded

Blinding description

The list of random allocation of patients will be available only to the epidemiologist of the project. To hide the random allocation process, the order of interventions will be written on 126 cards and each card will be placed in an envelope (with a suitable thickness that it is not possible to read the type of intervention on the cover of the envelope). When the interviewer declares a baby eligible, the methodologist will provide the group with an intervention plan. The person evaluating the intended outcomes is a third party who is unaware of the random allocation process and the type of treatment performed. For data analysis, a statistician who is separate from the study process and is unaware of all the processes performed will be used.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Mahdieh St. Research Square Shahid Fahmideh St. University of Medical Sciences and Health Services Vice Chancellor for Research and Technology

City

Hamedan

Province

Tehran

Postal code

6517838687

Approval date

2021-09-04, 1400/06/13

Ethics committee reference number

IR.UMSHA.REC.1400.466

Health conditions studied

1

Description of health condition studied

The effect of colostrum on the short-term prognosis of preterm infants

ICD-10 code

P07.3

ICD-10 code description

Preterm [premature] newborn [other]

Primary outcomes

1

Description

Duration of preterm neonatal hospitalization

Timepoint

From the time of birth and hospitalization to the time of discharge

Method of measurement

Extract from the file

2

Description

How long it takes for a baby to be fully breastfed

Timepoint

From the onset of colostrum to breastfeeding 150 cc per

kilogram of body weight

Method of measurement

Extract from the file

3

Description

Necrotizing enterocolitis in preterm infants

Timepoint

Since diagnosis based on clinical and radiological and laboratory symptoms

Method of measurement

Extraction from the file and clinical signs and radiological evidence recorded in the file

4

Description

Death of neonate

Timepoint

If there is no response to resuscitation and cardio-respiratory arrest

Method of measurement

Extract from file

5

Description

Confirmed neonatal sepsis

Timepoint

Since the diagnosis of neonates with clinical signs of sepsis with positive culture

Method of measurement

Extract blood and crp culture tests from hospital records and electronic systems

6

Description

clinical neonatal sepsis

Timepoint

Infant with clinical signs of sepsis diagnosed by a pediatrician

Method of measurement

Extract from file

7

Description

Brain hemorrhage

Timepoint

Brain sonography

Method of measurement

extract from file

8

Description

Bronchopulmonary dysplasia

Timepoint

Since the doctor's diagnosis and oxygen dependence

Method of measurement

Extract from file

9

Description

ROPs requiring laser surgery

Timepoint

Since the diagnosis of the eye to the doctor based on the need for laser surgery until 1 month old

Method of measurement

Extract from file

10

Description

Ventilator-associated pneumonia

Timepoint

Based on physician's diagnosis and radiographic findings

Method of measurement

Extract from file

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 63 infants received 0.2 cc of their mother's colostrum via the oropharynx every 6 hours to 3 days from birth to the first 72 hours of birth.

Category

Prevention

2

Description

Control group: The other 63 infants were placebo and received 0.2 cc of distilled water.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan Fatemieh Hospital

Full name of responsible person

Ameneh Iamsehchi

Street address

Hamedan.Pasedaran street

City

Hamedan

Province

Tehran

Postal code

65179 97178

Phone

+98 81 3827 7459

Email

vc_research@umsha.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Vice Chancellor for Research and Technology of Hamadan University of Medical Sciences
Street address
Hamedan. Shahid Fahmideh Blvd. Hamedan University of Medical Sciences. Deputy of Research and Technology.
City
Hamedan
Province
Tehran
Postal code
6717838687
Phone
+98 81 3838 1938
Email
Webda@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Ameneh Lamsehchi
Position
Non-faculty specialist
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
Hamadan Province, Hamedan, District 1, Pasdaran Ave,
City
Hamedan
Province
Tehran
Postal code
۶۵۱۷۷۸۹۹۷۱
Phone
+98 81 3827 7459
Email
lamsehchila@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
behnaz basiri
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Hamadan Province, Hamedan, District 1, Pasdaran Ave
City
Hamedan
Province
Tehran
Postal code
۶۵۱۷۷۸۹۹۷۱
Phone
+98 81 3827 7459
Email
vc_research@umsha.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Ameneh Lamsehchi
Position
non-faculty specialist
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
Hamadan Province, Hamedan, District 1, Pasdaran Ave,
City
Hamedan
Province
Tehran
Postal code
۶۵۱۷۷۸۹۹۷۱
Phone
+98 81 3827 8080

Email
lamsehchila@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable