Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparison of the effect breast milk odor and another breast milk odor on responses behavioral of pain caused by hepatitis B vaccination in premature neonates admitted to the Neonatal

Protocol summary

Study aim
Comparison of the effect breast milk odor and another breast milk odor on responses behavioral of pain caused by hepatitis B vaccination in premature neonates admitted to the Neonatal.

Design
The is a single-blind, randomized clinical trial study, so that observer evaluating pain response was not aware of which intervention had been administrated.

Settings and conduct
Every 2- 4 day, premature newborn get the first dose of hepatitis B vaccination at Ayatollah Rohani Hospital of Babol. Vaccine injection in all three groups under the same conditions, with the same and the same type of device is done.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having 28 to 34 weeks gestational age, Minimum age of 2 days, Not having asphyxia, Not having any congenital malformation especially in the nose area, Not being under mechanical ventilation or CPAP.
Exclusion criteria: Having neuromuscular complications and congenital abnormalities.

Intervention groups
Group 1: Newborns of the first group, 3 minutes before the study will be familiarized with their mother's milk odor by a sterile swap perfumed which its distance from the neonate's nose is 3 cm. Group 2: Newborns of the second group, 3 minutes before the study will be familiarized with another mother's milk odor by a sterile swap perfumed which its distance from the neonate's nose is 3 cm. Group 3: Newborns of the third group, 3 minutes before the study will be familiarized with Distilled water odor by a sterile swap perfumed which its distance from the neonate's nose is 3 cm.

Main outcome variables
Behavioral pain responses

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190220042771N1**
Registration date: **2019-05-18, 1398/02/28**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-18, 1398/02/28**
Update count: **0**

Registration date
2019-05-18, 1398/02/28

Registrant information

Name
Adeleh Saebi Amiri

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-26, 1397/12/07

Expected recruitment end date
2021-02-25, 1399/12/07

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect breast milk odor and another breast milk odor on responses behavioral of pain caused by hepatitis B vaccination in premature neonates admitted to the Neonatal

Public title
The effect breast milk odor response to pain caused by hepatitis B vaccination

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having 28 to 37 weeks gestational age Minimum age is 2 days Have not asphyxia Haven't any congenital malformation Especially in the nose area Not be under mechanical ventilation or CPAP

Exclusion criteria:
Baby will be deleted from the study if the diagnosis neuromuscular complications and congenital abnormalities.

Age
From **2 days** old to **4 days** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the neonates into three groups with a table of random numbers (A random number table is a collection of numbers that are generated without a specific pattern or order and completely randomized, then samples are randomly selected by Randomizer software).

Blinding (investigator's opinion)
Single blinded

Blinding description
The is a single-blind, randomized clinical trial study, so that observer evaluating pain response was not aware of which intervention had been administrated.

Placebo
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
Daneshgah Square, Ganjafrooz Avenue

City
Babol

Province
Mazandaran

Postal code
47176-47745

Approval date
2019-01-23, 1397/11/03

Ethics committee reference number
IR.MUBABOL.HRI.REC.1397.253

Health conditions studied

1

Description of health condition studied
The Pain of vaccine

ICD-10 code
M79.6

ICD-10 code description
Pain in limb, hand, foot, fingers and toes

Primary outcomes

1

Description
Behavioral pain responses

Timepoint
3 minutes before vaccination until the end of the vaccination

Method of measurement
PIPP (Premature infant pain profile) standard tool

Secondary outcomes

empty

Intervention groups

1

Description
Newborn's of the first group, 3 minutes before the study will be familiarized with their mother's milk odor by a sterile swap perfumed which its distance from the newborn's nose is 3 cm.

Category
N/A

2

Description
Newborn's of the second group, 3 minutes before the study will be familiarized with another mother's milk odor by a sterile swap perfumed which its distance from the newborn's nose is 3 cm.

Category
N/A

3

Description
Newborn’s of the third group, 3 minutes before the study will be familiarized with Distilled water odor by a sterile swap perfumed which its distance from the newborn’s nose is 3 cm.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rouhani Hospital
Full name of responsible person
Dr. Parvin Aziznejad Roshan
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Mazandaran, Babol, Ganj Afrooz Avenue, Babol University of Medical Sciences.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
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Dr Reza Ghadimi
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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
Full name of responsible person
Adele Seibi Amiri
Position
Master's student of neonatal intensive care nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for updating data

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Position
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Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available