

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 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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+98 11 3219 0597

Email address

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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

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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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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Babol University of Medical Sciences

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

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 scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity
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Other areas of specialty/work
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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