Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of Breast Milk and Vanilla Odor Venipuncture Response to Pain in Preterm Infants 28-34 Weeks: Control Randomised Clinical Trial

Protocol summary

Summary

The aim of this study is to compare the effect of mother's milk odor and Vanilla on Pain control in venous Pancture in Preterm Newborn and it is Control single blind study.150 newborn that have conditions(28 to 34 weeks gestational age, mother's milk fed, having experienced the pain of previous sampling, drink milk or sweet liquids 30 minutes before the intervention) be randomly divided into three groups. Newborns of the first group 9-16 hours before the study will be familiarized with their mother's milk odor by an sterile swap perfumed with mother's milk which its distance from the infant's nose is 10 cm and Newborns of the second group will be familiarized with a vanilla smell by an sterile swap perfumed with 10 drops of vanilla Dissolved in glycerol and infants in the control group no intervention will not be performed on them. Day of the study first and second and third groups of infants during the 5 minutes before blood sampling, during sampling and 5 minutes after blood sampling by an sterile swap perfumed with mother's milk, vanilla Dissolved in glycerol, sterile water will be exposed to the Intended smell from 1 cm distance without contact with the infant's nose. Researchers will record baby's physiological and behavioral responses by two camcorder and two Researchers that Do not information about infants allocated to the groups will be evaluated Neonatal pain response using PIPP tool based on the recorded movies.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203086918N5**
Registration date: **2012-08-04, 1391/05/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-08-04, 1391/05/14

Registrant information

Name
Alehe Seyedrasooli
Name of organization / entity
Faculty of Nursing & Midwifery
Country
Iran (Islamic Republic of)
Phone
+98 41 1479 0365
Email address
seyyedrasooly@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy for research of Tabriz University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2012-12-20, 1391/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Breast Milk and Vanilla Odor Venipuncture Response to Pain in Preterm Infants 28-34 Weeks: Control Randomised Clinical Trial

Public title

olphactory stimulations and pain control in newborn

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:Having 28 to 34 weeks gestational age; Minimum age is 3 days, mother's milk fed; having experienced the pain of previous sampling; drink milk or sweet liquids 30 minutes before the intervention; have not asphyxia, they have stability With specialist neonatal physiologic view; haven't any congenital malformation Especially in the nose area; haven't IVH or PVL; haven't need to surgery; without mecanical ventilation or CPAP; Baby's have willingness to participate in the study و Exclusion criteria:Baby will be deleted from the study if the diagnosis neuromuscular complications and congenital abnormalities or create any item that would violate the entry criteria; Baby will be deleted from the study if it is not successful obtaining a blood sample with a disposable needle into the skin and need to again try from sampling; Baby will be deleted from the study if recorded films during the intervention are obscure.

Age

To **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

tabriz-the end of golgasht street

City

tabriz

Postal code

Approval date

2012-06-30, 1391/04/10

Ethics committee reference number

9144

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

P07.3

ICD-10 code description

Other preterm infants. 28 completed weeks or more but less than 37 completed weeks (196 completed days but less than 259 completed days) of gestation. Prematurity NOS

Primary outcomes

1

Description

pain

Timepoint

5 minute before blood sampling and during blood sampling and 5 minute after sampling

Method of measurement

with PIPP standard tool

Secondary outcomes

empty

Intervention groups

1

Description

Newborns of the mother milk group 9-16 hours before the study will be familiarized with their mother's milk odor by an sterile swap perfumed with mother's milk which its distance from the infant's nose is 10 cm. Day of the study this group of infants during the 5 minutes before blood sampling, during sampling and 5 minutes after blood sampling by an sterile swap perfumed with mother's milk will be exposed to the Intended smell from 1 cm distance without contact with the infant's nose and will be evaluated Neonatal pain response using PIPP tool based on the recorded movies. .

Category

Prevention

2

Description

Newborns of the vanilla group 9-16 hours before the study will be familiarized with vanilla Dissolved in glycerol odor by an sterile swap perfumed with vanilla Dissolved in glycerol which its distance from the infant's nose is 10 cm. Day of the study this group of infants during the 5 minutes before blood sampling, during sampling and 5 minutes after blood sampling by an sterile swap perfumed with vanilla Dissolved in glycerol will be exposed to the Intended smell from 1 cm distance without contact with the infant's nose and will be

evaluated Neonatal pain response using PIPP tool based on the recorded movies. .

Category

Prevention

3

Description

Newborns of the control group will not be familiarized with any odor before the study . Day of the study this group of infants during the 5 minutes before blood sampling, during sampling and 5 minutes after blood sampling filmed Whereas will be an sterile swap perfumed with sterilel water on 1 cm distance without contact with the infant’s nose and will be evaluated Neonatal pain response using PIPP tool based on the recorded movies. .

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Educational Center Affiliated Tabriz university of Medical Sciences ;Iran

Full name of responsible person

zahra gaffari

Street address

tabriz- artesh street - Bagshomal Square

City

tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Rashidi

Street address

Central Building of Tabriz University of Medical Sciences,Golgasht Avenue, azadi street,Tabriz

City

tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nursing & Midwifery of Tabriz

Full name of responsible person

Seyedrasooli Alehe

Position

MSC of mother and child Hygiene

Other areas of specialty/work

Street address

South Shariety St ; Faculty of Nursing & Midwifery ; Tabriz ; Iran

City

tabriz

Postal code

Phone

+98 41 1479 0365

Fax

Email

seyyedrasooly@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty