

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparing The Effect Of Sucrose Taste, Maternal Breast Milk Odor And Taste On The Pain Associated With Venous Blood Sampling In Neonate

Protocol summary

Study aim

Comparing the effect of sucrose taste, maternal breast milk odor and taste on the pain associated with venous blood sampling in neonate

Design

In this study 90 newborns with jaundice diagnosis and inclusion criteria are selected. Participants randomly divided into three groups: breast milk odor, breast milk and sucrose tasting, and each participant will be assigned a code.

Settings and conduct

This study is carried out at Bu-Ali Sina hospital in Sari. At sampling, samples of all three groups are resting in the back under the Radiant heater in a quiet room with mild light and feeding with breast milk at least one hour before intervention. All infants undergo continuous monitoring of heart rate and arterial oxygen saturation before and during the study. In the sucrose taste group, 2 cc sucrose 24%, 3 minutes before the procedure is poured into the front of the infant's nose. In the maternal breast milk group, the 2-cc breast milk was infused by the syringe in the front of the baby's mouth 3 minutes before blood sampling. In order to bloom, in the sucrose flavor and the milk flavor group, the bullet is stained with normal saline, along with the nose. In the breast milk odor group, 2 cc of milk was poured on cotton balls for 3 minutes before to 30 seconds after blood sampling. 2 ml of normal saline is also infused into the baby's language 3 minutes before the procedure. The relevant questionnaires will be filled in by a person familiar with the pain assessment after interpreting the sampling film.

Participants/Inclusion and exclusion criteria

Neonates with gestational age 37 to 40 weeks, stable for vital signs, with jaundice diagnosis, no congenital anomalies, such as cleft palate and lumbar spine and choanal atresia, full vigilance, no other painful procedure before intervention, no feeding within a time interval Less than an hour before the intervention and the baby is not fasting. Non-refusal to continue to participate in

research by parents, recipient of Pain killer drug, sedation and anticonvulsants, without abnormalities in the head and skull, and failure in venous sampling at first time

Intervention groups

Mother Milk Odor Group
Mother Milk tasting group
Sucrose tasting group

Main outcome variables

Pain variable

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170821035820N1**

Registration date: **2017-12-12, 1396/09/21**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-12, 1396/09/21**

Update count: **0**

Registration date

2017-12-12, 1396/09/21

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

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a.modaresi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-16, 1396/06/25

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing The Effect Of Sucrose Taste, Maternal Breast Milk Odor And Taste On The Pain Associated With Venous Blood Sampling In Neonate

Public title

Comparing The Effect Of Sucrose Taste, Maternal Breast Milk Odor And Taste On The Pain Associated With Venous Blood Sampling In Neonate

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Babies with gestational age 37 to 42 weeks Sustained in terms of vital signs With Diagnosis of icter Complete vigilance

Exclusion criteria:

Fasting Receive nutrition within less than an hour before the intervention Get another painful procedure before the intervention Congenital abnormalities such as cleft palate, lumbar spine and atresia quan Refuse to continue to participate in research by parents Abnormalities in the head and skull Failure in venous blood sampling at first time

Age

From **2 days** old to **30 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Infants are randomly assigned to one of the three study groups with the help of a random number table and receive the intervention of the same group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Infants' parents and outcome evaluators are unaware of the patient's exposure. In each of the three groups, the cotton balls were stained with normal saline or milk for 3 minutes before 30 seconds after the sampling was placed next to the nose of the baby, and 2 cc normal saline or milk with 2 cc syringe also 3 minutes before the The procedure is poured on the language of the baby.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethics Committee of Babol University of Medical Sciences

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Ganj Afroz Street

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Approval date

2017-06-25, 1396/04/04

Ethics committee reference number

mubabol.hri.rec.1396.9

Health conditions studied**1****Description of health condition studied**

Comparing the effect of sucrose taste, maternal breast milk odor and taste on the pain associated with venous blood sampling in neonate

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain

Timepoint

During intervention, After intervention

Method of measurement

Neonatal Infant Acute Pain Assessment Scale

Secondary outcomes**1****Description**

Arterial oxygen saturation

Timepoint

Before intervention, during intervention, after

intervention
Method of measurement
Mobile monitoring device

2

Description

Heart rate

Timepoint

Before intervention, during intervention, after intervention

Method of measurement

Mobile monitoring device

Intervention groups

1

Description

Intervention group: In the milk odor intervention group, 2 cc of milk was poured into cotton balls and placed for 3 minutes before to 30 seconds, and 2 cc of normal saline was poured into the baby's language 3 minutes before the procedure.

Category

Prevention

2

Description

Intervention group: In the group, the taste of sucrose, 2 cc sucrose 24%, is cast 3 minutes before the procedure in the front part of the baby's nose, and the cotton bullet stained with normal saline is placed next to the nose.

Category

Prevention

3

Description

Intervention group: In the breast milk taste group, 2-cc of maternal milk, by the syringe, is cast in the front of the baby's tongue 3 minutes before sampling, and the cotton ball covered with normal saline was placed next to the baby's nose.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Buali Sina Hospital

Full name of responsible person

Asiyeh Modaresi

Street address

Bu-Ali Sina Hospital, Imam Square, Pasdaran Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Research Assistance

Street address

Ganj Afrouz Avenue, Babol University of Medical Sciences and Health services, Deputy Head of Research & Technology

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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

Asiyeh Modaresi

Position

Master's student nursing specialist neonates

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available