

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

the effect of breast milk odor on physiological and behavioral responses following venous blood

Protocol summary

Study aim

En the effect of breast milk odor on physiological and behavioral responses following venous blood

Design

Clinical trial with control group, with parallel groups, Two blind, randomized, with a sample size of 30

Settings and conduct

The impact of breastfeeding on physiological and behavioral responses following term infant venous blood sampling begins at the time of admission to Torbat-e-Heydariyeh Hospital. Nutrition training, pharmacy training, breastfeeding training, etc. are provided during the stay. Education is provided by a nurse with the help of a pamphlet, a medical booklet, and so on. The training is conducted after telephone discharge and lasts up to 12 weeks after discharge.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-to-3 days 2-weight 2 to 5 g Non-Inclusion conditions: 1-Not willing to continue research.

Intervention groups

Intervention group: 531/5000 In the mother's smell group, the infant will be used to stimulate the baby's olfactory odor, first in the morning before eating breakfast, then 2 cc of milk will be poured on the napkin and placed 2 cm from the baby's nose. This begins about 5 minutes before heel blood sampling and will continue until the procedure is completed. Physiological data (heart rate and arterial oxygen saturation percentage) will be recorded by pulse oximeter immediately before the intervention as baseline and immediately after the intervention when the heel blood sampling is completed.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191130045557N1**

Registration date: **2020-04-23, 1399/02/04**

Registration timing: **prospective**

Last update: **2020-04-23, 1399/02/04**

Update count: **0**

Registration date

2020-04-23, 1399/02/04

Registrant information

Name

Hamideh Yaghoobi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5224 2463

Email address

hamideh.yaghoobi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of breast milk odor on physiological and behavioral responses following venous blood

Public title

the effect of breast milk odor on physiological and

behavioral responses

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age 3-5 days Weight 2500 to 3500 grams
Exclusion criteria:
Do not want to participate in research.

Age
From **3 days** old to **5 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization: Simple randomization, using 174-bit Random Excel software with Excel, is generated sequentially with A and B bursts. The reader now has a patient range of 1 to 30, depending on whether he is in either of the A or B grades, in either of these two groups of patients.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Torbat Heydariyeh University of Medical Sciences

Street address

Torbat Heydariyeh University of Medical Sciences Building., Razi St., Ferdawsi St.

City

Torbat Heydarieh

Province

Razavi Khorasan

Postal code

95196-33787

Approval date

2020-02-29, 1398/12/10

Ethics committee reference number

IR.THUMS.REC.1398.050

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

pain will be measured once before the first intervention and once after the last intervention session.

Method of measurement

Visual scale of pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 531/5000In the mother's smell group, the infant will be used to stimulate the baby's olfactory odor, first in the morning before eating breakfast, then 2 cc of milk will be poured on the napkin and placed 2 cm from the baby's nose. This begins about 5 minutes before heel blood sampling and will continue until the procedure is completed. Physiological data (heart rate and arterial oxygen saturation percentage) will be recorded by pulse oximeter immediately before the intervention as baseline and immediately after the intervention when the heel blood sampling is completed.

Category

N/A

2

Description

Control group: Except for the usual self-care training that all infants receive, no further action will be taken.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Nohome day Hospital, Torbat Heydarieh University of Medical Sciences

Full name of responsible person

Hamideh Yaghoobi

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Torbat Heydariyeh University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Dr Hasann Azhdari Zarmehri

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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

Torbate-Heidaria 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**

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Hamideh Yaghoobi

Position

Member of the faculty of Torbat Heydarieh University
of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Nursery

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the main consequence after being
unidentified will be shared

When the data will become available and for how long

Start the access period 6 months after Publish results

To whom data/document is available

Everyone

Under which criteria data/document could be used

The results obtained in this study can be used without
restriction by researchers.

From where data/document is obtainable

Referring to Torbat Heidarieh Nursing and Midwifery
Faculty

What processes are involved for a request to access data/document

After sending the email to the person responsible for the
response process begins.

Comments