

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Effect of breast milk odor on physiologic parameter and weight in premature neonate

Protocol summary

Summary

Background and Aim: Many of premature infant suffer from disabilities such as intellectual, somatic even nervous and psychic during their life. Their condition depends on their growth medium. To reduce these effects, using olfactory stimulation should be one of important nursing care in NICU. So the aim of this paper was to detect: the effect of breast milk odor and formula odor on physiologic parameter and weight changes in premature born infants. Method: This study is controlled trial. The research population are 180 premature infant with gestational age 30-34 weeks of Hazrat Zeinab hospital in Shiraz. Olfactory Interventions with breast milk, formula odor and distill water will be done for three experimental group. The control group has no olfactory stimulation. The intervention will be done in 120 second, twice a day for the first week after birth. Data analysis will be done with repeated measurement, one way ANOVA and kruskal Wallis test.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2014070818397N1**

Registration date: **2014-09-03, 1393/06/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-03, 1393/06/12

Registrant information

Name

Seyedeh Narjes Dehghanian

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 72 8222 9690

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dehghaniann901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhd University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2014-09-20, 1393/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of breast milk odor on physiologic parameter and weight in premature neonate

Public title

clinical trial, effect of breast milk odor and formula milk odor and distilled water on physiologic parameter and weight changes in premature infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 24 hours after birth; gestational age 30 until 34 at birth; caring in incubator; Stable physiologic parameter; body temperature 36.2 until 37.2; Apgar higher than 7 at minute 5 after birth; spontaneous respiration infant does not need ventilator; the mother does not smoke cigarette or use drugs and alcohol; no

sign of major congenital abnormality and infection.
Exclusion criteria: the parents don't like to continue participation in research; secondary infection; convulsion; recurrent apnea; need to ventilator or cpap; Intraventricular hemorrhage grade 3 or 4 based on brain sonography on third day ; discharge and expire before completion of intervention.

Age

To **7 days** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

randomize was done with random number

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

2

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Daneshgah Avenue, Mashhad

City

Mashhad

Postal code

Approval date

2013-09-23, 1392/07/01

Ethics committee reference number

920831

2

Ethics committee

Name of ethics committee

mashhad university of medical science

Street address

ebn-e - sina avenue

City

mashhad

Postal code

9137913199

Approval date

2013-09-23, 1392/07/01

Ethics committee reference number

920831

Health conditions studied

1

Description of health condition studied

PHYSIOLOGIC PARAMETER AND WEIGHT

ICD-10 code

XXI

ICD-10 code description

Factors influencing health status and contact with health services

Primary outcomes

1

Description

weight

Timepoint

daily for 1 week

Method of measurement

gram

2

Description

heart rate

Timepoint

before and after stimulation, twice a day for 1 week

Method of measurement

beat/ min

Secondary outcomes

1

Description

respiratory rate

Timepoint

during stimulation, twice a day for 1 week

Method of measurement

beat/min

Intervention groups

1

Description

1-Intervention group1: breast milk odor, 1.5 cc of breast milk odor pour on a 4*4 gauze put in 3 centimeters far from infants nostril.

Category

Prevention

2

Description

2-Intervention group2: formula odor, 1.5 cc of just diluted formula milk from Bebelac company pour on a 4*4 gauze put in 3 centimeters far from infants nostril.

Category

Prevention

3

Description

3-Intervention group3: distilled water, 1.5 cc of distilled water pour on a 4*4 gauze put in 3 centimeters far from infants nostril.

Category

Placebo

4

Description

4- control group: no intervention will be done and just expose to environmental odor.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Zeinab Hospital

Full name of responsible person

Dr. Shahnaz Pourarian

Street address

Defa moghadas square, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Science

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

College of Pharmacy, Pardis daneshgah, Vaikil abad bolvar, Mashhad

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Science

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

Name of organization / entity

Mashhad University of Medical Science

Full name of responsible person

Narjes Dehghanian

Position

student postgraduate

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Science

Full name of responsible person

Soheila Karbandi

Position

Master of Science Degree

Other areas of specialty/work

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Person responsible for updating data

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Position

Master of science student

Other areas of specialty/work

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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