

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of music therapy on breast milk secretion in premature infant mothers hospitalized in neonatal intensive care unit of Hazrat Zeinab (SA) Shiraz

Protocol summary

Summary

The intervention study do in two stages for 4 days in two shifts, morning and afternoon. In this case, the amount of breast milk is measured with music and without music. Measuring the amount of milk will start from the third day after delivery. In the first phase and the fourth consecutive day, in two shifts, morning and afternoon mothers with the the standard of nursing care listening to instrumental music in 30 minutes (15 minutes before and 15 minutes during with breast milk by milkmaids). Immediately after the first stage do the second stage. In this case, the previous mothers fourth consecutive day do breast milk by milkmaids for 15 minutes without music. In the end, mean and variation in expressed breast milk can be compared in two stages.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060628303N1**

Registration date: **2017-03-17, 1395/12/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-17, 1395/12/27

Registrant information

Name

Zeinab Zarei

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4257

Email address

zezarei@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Department of Shiraz University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of music therapy on breast milk secretion in premature infant mothers hospitalized in neonatal intensive care unit of Hazrat Zeinab (SA) Shiraz

Public title

The effect of music therapy on breast milk secretion in premature infant mothers

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria for the study: Mothers consent to participate in the study; Mothers of babies with a gestational age of 28 to 34 weeks; Do not use medications that decrease or increase the secretion of milk; The absence of severe hearing problems in mothers; Lack of substance abuse by the mother; No previous surgery on breast; Do not feed the baby through the breast; Lack of mental health problems in

the mother Exclusion criteria for the study: Not consent to continue cooperation mothers during the study; Discharge newborns during the study;The baby died during the study; Create problems in breast-fed during the study; use medications that decrease or increase the secretion of milk during the study; Create severe hearing problem in mothers during the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 35

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

For the same conditions of study for all the mothers in the study used a same milk vacuum before study, Mothers will be trained to use the milkmaids.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences.Zand street,Shiraz

City

Shiraz

Postal code

713451978

Approval date

2016-11-06, 1395/08/16

Ethics committee reference number

IR.SUMS.REC.1395.141

Health conditions studied

1

Description of health condition studied

amount of secretion breast milk

ICD-10 code

P92.5

ICD-10 code description

Neonatal difficulty in feeding at breast

Primary outcomes

1

Description

Premature infant mothers breast milk

Timepoint

15 minutes after intervention

Method of measurement

amount of milk according ml, use measure

Secondary outcomes

empty

Intervention groups

1

Description

Milk by milking,For 8 days and every day 2 times,4 days with music,4 The second day without music

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Zeinab (SA)

Full name of responsible person

Zeinab Zarei_nursing bachelor

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Research Department,Shiraz University of Medical Sciences

Street address

Seventh floor, Shiraz University of Medical Sciences.Zand Street

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Shiraz 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****Name of organization / entity**

University of Nursing and Midwifery Hazrate
Fatemeh(SA) Shiraz

Full name of responsible person

Mitra Edraki

Position

Master neonates_Faculty member

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Shiraz Medical Sciences

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Position

Nursing bachelor

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Web page address**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