

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of yoga on the volume and composition of breast milk in premature infants

Protocol summary

Study aim

Determining the effect of yoga on the volume and composition of breast milk in premature infants admitted to the neonatal intensive care unit

Design

Random Allocation Software was used for randomized clinical trial with functional groups with functional groups, blind one-way, randomized, on 78 mothers.

Settings and conduct

In the control group, after routine breastfeeding training, sampling is done by a trained researcher. For all mothers in the control group, sampling is done on the first and sixth day. In the second group (yoga), in addition to routine breastfeeding training, mothers are taught yoga relaxation techniques by a yoga specialist from the first day of study to the sixth day in the presence of a researcher in a quiet room separate from the neonatal ward. The duration of yoga intervention is 45 minutes every day for 6 consecutive days after routine breastfeeding training. For all mothers in the intervention group on the first and sixth days after the end of the class, milk samples are collected and measured through an electric milk pump and 5 ml of milked breast milk is stored at -80 degrees in the University Research Center. Blinding has been done on a laboratory evaluator and an analyst.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Be primiparous; Intrauterine age below 34 weeks; Mothers who spend 4-6 days after giving birth
Exclusion criteria: Multiplication

Intervention groups

The study is done in two groups. In the first intervention group, participants receive yoga techniques by yoga treatment for 6 consecutive days in addition to routine breastfeeding training, and in the second intervention group, participants receive routine breastfeeding training alone.

Main outcome variables

The primary consequence is the effect of yoga on the

volume of milk of mothers with premature infants.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220104053619N1**

Registration date: **2022-01-19, 1400/10/29**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-19, 1400/10/29**

Update count: **0**

Registration date

2022-01-19, 1400/10/29

Registrant information

Name

fatemeh karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3232 5887

Email address

karimifateme711@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-10, 1400/10/20

Expected recruitment end date

2022-11-11, 1401/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of yoga on the volume and composition of breast milk in premature infants

Public title

The effect of yoga on breast milk

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Maternal desire to participate in research Breastfeeding by mother Possibility of mother for breastfeeding during the day Intrauterine age below 34 weeks Written order from the doctor stating that breastfeeding is allowed by the mother To be primiparous means not to have a previous pregnancy that even leads to abortion. Mothers who spend 4-6 days after giving birth

Exclusion criteria:

Anatomical problems in the breast such as nipple sagging and fissures and mastitis Smoking and addiction Taking drugs that affect milk production Mothers with active tuberculosis and AIDS Mothers who have had breast surgery Mothers who have postpartum depression or experience a life crisis or sedative. Mothers who consume lactating compounds Mothers on treatment regimens and vegetables (vegetarian). History of exercise or yoga during the last 3 months Use of effective contraceptive methods on breastfeeding

Age

From **4 days** old to **6 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **78**

More than 1 sample in each individual

Number of samples in each individual: **2**

Samples are taken from each participant twice, once on the first day and once on the sixth day.

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned to one of two control and intervention groups in a ratio of 1: 1. Randomization is block randomization with blocks of size of 6. According to the random block division protocol (produced by Random Allocation Software), so that the researcher can not predict Slowly the next person in which group of intervention is placed. The codes will be placed inside the matte envelopes, respectively, and with the arrival of each new person, the envelope is opened and the person's belonging to the relevant group is determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, due to the fact that after randomization, both mothers and researchers can not be blinded (because the type of intervention is known), so blinding can not be done in the first stage. On the other hand, measuring all the consequences in this study is objective and laboratory. Blinding will only be done for the laboratory evaluator and data analyst.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences.Ganj Afrooz St

City

Babol

Province

Mazandaran

Postal code

47176-47745

Approval date

2022-01-03, 1400/10/13

Ethics committee reference number

IR.MUBABOL.HRI.REC.1400.169

Health conditions studied

1

Description of health condition studied

The effect of yoga on the volume and composition of milk of mothers with premature infants

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Determining the effect of yoga on breast milk volume in mothers of premature infants admitted to neonatal intensive care unit

Timepoint

Measurement of milk volume at the beginning of the study (first day) and the end of the study (sixth day)

Method of measurement

The volume of milk is measured using milk milked by an electric milking machine in a calibrated container.

Secondary outcomes

1

Description

Determining the effect of yoga on breast milk fat in mothers of premature infants admitted to neonatal intensive care unit

Timepoint

Measurement of breast milk fat based on the samples of the first day of the study and the sixth day of the study

Method of measurement

Cholesterol and triglyceride levels in breast milk were evaluated using a laboratory test

2

Description

Determining the effect of yoga on breast milk total protein in mothers of premature infants admitted to neonatal intensive care unit

Timepoint

Measurement of breast milk total protein using milk samples on the first and sixth days of the study

Method of measurement

Using laboratory amounts of total protein in milk samples

3

Description

Determining the effect of yoga on breast milk albumin in mothers of premature infants admitted to neonatal intensive care unit

Timepoint

Measurement of breast milk albumin based on the samples of the first day of the study and the sixth day of the study

Method of measurement

Study using laboratory values of albumin in milk samples of the first and sixth days

4

Description

Determining the effect of yoga on breast milk calcium in mothers of premature infants admitted to neonatal intensive care unit

Timepoint

Measurement of breast milk calcium based on the samples of the first day of the study and the sixth day of the study

Method of measurement

Using laboratory values of calcium in milk samples on the first and sixth days of the study

5

Description

Determining the effect of yoga on breast milk phosphorus in mothers of premature infants admitted to neonatal intensive care unit

Timepoint

Measurement of breast milk phosphorus based on the

samples of the first day of the study and the sixth day of the study

Method of measurement

Using laboratory amounts of phosphorus in milk samples of the first and sixth days of the study

6

Description

Determining the effect of yoga on the weight of infants admitted to the neonatal intensive care unit

Timepoint

Measure the baby's weight on the first and sixth days

Method of measurement

Measure the baby's weight using a digital scale on the first and sixth days of the study

Intervention groups

1

Description

In the intervention group (yoga), 39 mothers were included in the study according to the inclusion criteria. In addition to teaching routine breastfeeding, mothers are taught yoga relaxation techniques by a yoga specialist from the first day to the sixth day in the presence of the researcher in a quiet room separate from the neonatal ward located in the gynecology clinic of Ayatollah Rouhani Hospital in Babol. It is given to include: 1- Exercising the muscles around the chest for 10 minutes while sitting on a chair 2- Asana movements while sitting on a chair for 5 minutes 3- Deep and gentle breathing with chest movements while sitting on a chair 5 minutes 4 - Relax for 25 minutes in a quiet and low light environment with a gentle song played by the laptop and lying on the floor. During the yoga intervention every day for 45 minutes for 6 The consecutive day after training is breastfeeding routine. For all mothers in the intervention group, on the first and sixth days after the end of the routine breastfeeding training class and performing the yoga relaxation technique, sampling is done between 11-12: 30 by milking with an electric breastmilk by Mami Wack, made in Germany, and the sample Our studies are selected from the second breastfeeding, which is three hours away from the first, and are measured in a non-sterile calibrated glass container by the first researcher and recorded in terms of volume in the questionnaire, and 5 ml of breast milk by The sterile syringe is taken and placed in a container containing an ice pack to be transferred to the freezer of the Biochemistry Laboratory of Babol University of Medical Sciences at -80 ° C for storage for biochemical tests. Glyceride), albumin and total protein, calcium and phosphorus with a spectrophotometer made in England, model (Unico 9344) with accurate measurement of mg / dl by a laboratory expert in the form of blind and for all samples centrifuged (by Clement 2000 available in the laboratory) according to the instructions Standard Mel Kit (Pars Azmoon made in Iran) is measured.

Category

N/A

2

Description

39 mothers with inclusion criteria who are on days 4-6 after delivery, in the control group after routine breastfeeding training by a trained researcher (student) and based on a checklist in the neonatal intensive care unit Takes. The mother first washes her hands and sits on a comfortable chair in the breastfeeding room. Environmental conditions such as dimming and protecting the fabric provide comfort to the mother. An explanation of the operation of the electric breast pump in the ward is given to the mother. The first milking time after the mother wakes up is around eight o'clock in the morning. The samples of our study are selected from the second breastfeeding, which is three hours away from the first. For all mothers in the control group, sampling is done fifteen minutes after the end of the routine breastfeeding training class at eleven and fifteen minutes on the first and sixth days. Milk is milked by German Mami Vak electric milking machine with the presence of a researcher and measured in a non-sterile graduated glass container based on milliliters by the first researcher and recorded with the name of mother and baby and milking time and milk volume and direction. Laboratory examination is kept at -80 ° C in the refrigerator of the biochemistry department of Babol University of Medical Sciences.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Rohani hospital

Full name of responsible person

Ebrahim Hejazian

Street address

Ayatollah Rouhani Hospital, Afrooz St, Babol Town

City

Babol

Province

Mazandaran

Postal code

47176-477745

Phone

+98 11 3219 9592

Fax

+98 11 3219 0181

Email

info@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Reza Ghadimi

Street address

Ganj Afrooz St

City

Babol

Province

Mazandaran

Postal code

47146-47745

Phone

+98 11 3219 7667

Fax

+98 11 3219 7667

Email

rezaghadimi@yahoo.com

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

50

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

Fatemeh Karimi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Ganj Afrooz St

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

009832325887

Fax

+98 11 3219 0181

Email
karimifateme711@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Fatemeh karimi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Ganj Afrooz St

City
Babol

Province
Mazandaran

Postal code
47176-47745

Phone
+98 11 3219 9592

Email
karimifateme711@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Fatemeh karimi

Position
Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address
Ganj Afrooz St

City
Babol

Province
Mazandaran

Postal code
47176-47745

Phone
+98 11 3232 5887

Email
karimifateme711@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available