

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The effect of Oketani massage on volume milk and breastfeeding behavior in premature infants admitted to neonatal intensive care unit

#### Protocol summary

##### Study aim

The aim of this study was to determine the effect of Oketani massage on volume milk and breastfeeding behavior in premature infants admitted to neonatal intensive care unit

##### Design

The quasi-experimental has control group, parallel group and non-randomized groups.

##### Settings and conduct

Oketani massage during first 6 hours after delivery for the intervention group for 20 minutes in the morning and evening for 3 consecutive days will be performed by the researcher in the rest room of the neonatal ward of Imam Reza and Ghaem hospitals. Data analysts and sample allocators to groups are not aware of the allocation of samples.

##### Participants/Inclusion and exclusion criteria

Entry Criteria: The age of the mother is between 20 and 35 years Be literate and be able to understand writing and verbal instructions The mother tends to breastfeed  
No entry Criteria: The mother has a history of serious and chronic illness such as cardiovascular disease or mental illness (postpartum depression, schizophrenia) according to the mother. The mother is addicted to drugs, especially cocaine and derivatives, according to the mother. The mother take medications that are contraindicated during breastfeeding, such as doxepin tricyclic antidepressants, iodine compounds, gold salts, salicylates, and anticonvulsants during the intervention. The mother has a history of breast surgery and no history of injuries or wounds at the massage site and no breast problems (breast fissures, congestion, mastitis and breast abscess). The mother take lactation-enhancing drugs, including metoclopramide.

##### Intervention groups

Intervention group: Oketani massage will be performed in three days after delivery, 6 hours after delivery (for 20 minutes in each session in the morning and evening) in the mothers' rest room. Control group: There is no

intervention in this group.

##### Main outcome variables

Milk volume and breastfeeding behavior

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201108049304N1**

Registration date: **2020-12-17, 1399/09/27**

Registration timing: **prospective**

Last update: **2020-12-17, 1399/09/27**

Update count: **0**

##### Registration date

2020-12-17, 1399/09/27

##### Registrant information

##### Name

Fatemeh Rezaei shoja

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3732 3236

##### Email address

rezaeisf971@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-21, 1399/10/01

##### Expected recruitment end date

2021-05-21, 1400/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
The effect of Oketani massage on volume milk and breastfeeding behavior in premature infants admitted to neonatal intensive care unit

**Public title**  
The effect of Oketani massage on breastfeeding

**Purpose**  
Other

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
The age of the mother is between at least 20 and at most 35 years Be literate and be able to understand writing and verbal instructions The mother tends to breastfeed

**Exclusion criteria:**  
The mother has a history of serious and chronic illness such as cardiovascular disease or mental illness (postpartum depression, schizophrenia) according to the mother. The mother is addicted to drugs, especially cocaine and derivatives, according to the mother. The mother take medications that are contraindicated during breastfeeding, such as doxepin tricyclic antidepressants, iodine compounds, gold salts, salicylates, and anticonvulsants during the intervention. The mother has a history of breast surgery and no history of injuries or wounds at the massage site and no breast problems (breast fissures, congestion, mastitis and breast abscess). The mother take lactation-enhancing drugs, including metoclopramide.

**Age**  
From **20 years** old to **35 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**

- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
In this study, data analysts and sample allocators to groups are not aware of the allocation of samples in each group.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

**Street address**

The central building of Mashhad University of Medical Sciences, Daneshgah St., Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91778-99191

**Approval date**

2020-11-17, 1399/08/27

**Ethics committee reference number**

IR.MUMS.NURSE.REC.1399.058

## Health conditions studied

### 1

**Description of health condition studied**

Fetus and newborn affected by other maternal noxious substances

**ICD-10 code**

P04.8

**ICD-10 code description**

Newborn (suspected to be) affected by other maternal noxious substances

## Primary outcomes

### 1

**Description**

The volume of mothers' breast milk

**Timepoint**

In the first to third days after delivery, half an hour before and after the intervention in the morning and evening

**Method of measurement**

Electric milking machine

### 2

**Description**

Breastfeeding behavior

**Timepoint**

Once in the first three days and once on the day of discharge and once at the end of the neonatal period (28 days) at the time of the mother's visit to examine the newborn

**Method of measurement**

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Oketani massage will be performed in three days after delivery, 6 hours after delivery (for 20 minutes in each session in the morning and evening) in the mothers' rest room. Oketani massage for the intervention group includes breast massage which includes a total of 8 hand techniques. Stage 1-7 is called a course of treatment, this step is done in 1 minute and repeated for 15-20 minutes. Step 1 Pressing and lifting the breast by the third finger of the right hand and the little finger of the left hand to the left shoulder, Step 2 Pressing and lifting the central part by the third finger of both hands to the armpit, Step 3 Pressing and lifting the breast by the third finger and sixty hands Right and third finger of the left hand and placing the thumb above the second joint of the thumb of the right hand, here pressing and pulling parallel to the opposite breast, these steps 1, 2 and 3 are to separate the firm part of the breast from the pectoralis major muscle, step 4 pressing the whole breast towards Umbilical cord, step 5 pulling the breast down to the right, step 6 pulling the breast down to the left, step 7 Turn the breast gently clockwise and pay attention to the elasticity of the breast base, step 8 milking the breast in four directions upwards.

#### Category

Other

### 2

#### Description

Control group: There is no intervention in this group.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghaem Hospital

##### Full name of responsible person

Mostafa Dastani

##### Street address

Ghaem Educational, Research and Treatment Center, Ahmadabad St., Dr. Shariati Square (Taghiabad), Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91871-45785

##### Phone

+98 51 3840 0000

##### Email

ghaem.hos@mums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital

##### Full name of responsible person

Ali Khorsand

##### Street address

Ebne Sina Street, Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91379-13316

##### Phone

+98 51 3854 3031

##### Email

imam.reza.hospital@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohsen Tafaghodi

##### Street address

The central building of Mashhad University of Medical Sciences, Daneshgah St., Mashhad

##### City

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##### Province

Razavi Khorasan

##### Postal code

91778-99191

##### Phone

+98 51 3841 2081

##### Email

presidentoffice@mums.ac.ir

#### 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 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Tahere Sadeghi

**Position**

Assistant Professor, Faculty Member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Fatemeh Rezaei shoja

**Position**

Nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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No.16,Sidi.4,Bilal.5,Imam Hossein Square,Mashhad Town

**City**

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**Province**

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**Postal code**

91778-99191

**Phone**

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**Fax****Email**

Rezaeisf971@mums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Tahere Sadeghi

**Position**

Assistant Professor, Faculty Member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Mashhad University of Medical Sciences, Daneshgah St., Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code****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**

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

**Statistical Analysis Plan**

Not applicable

**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