Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of Breast Massage on the Mother's Need for support During Lactation and Successful Breastfeeding in Neonates born through Cesarean Section in the Selected Hospitals Affiliated to Shahid Beheshti University Medical Sciences 2019.

Protocol summary

Study aim

Definition of the effect of breast massage on the mother's need for support during lactation and the successful breastfeeding in neonates born through cesarean Section

Design

Clinical trials include an intervention group and a control group that are randomly assigned in parallel

Settings and conduct

The context of this study was to determine the effect of breast massage on successful lactation in mothers of cesarean section and their need for support during lactation in selected hospitals of Shahid Beheshti University of Medical Sciences.

Participants/Inclusion and exclusion criteria

inclusion criteria 1.Single pregnancy 2.Maternal aged 18 to 35 3.Physical and mental illness is not based on mother's statement and file documentation 4.The gestational age is 37 to 41 weeks 5.There is no history of breast surgery, breast cancer, burn and scarring in the breast 6.There is not Prenatal illnesses, such as Gestational Diabetes(GDM), Preeclampsia, and viral diseases such as AIDS and Hepatitis. 7.There is not Prenatal abnormalities such as Placental abruption, Placenta Previa, heart and respiratory diseases.
exclusion criteria 1.severe hemorrhage during cesarean section 2.Uterine inertia and atony during cesarean section 3.use any drugs that Suppression lactation 4.The mother has no desire for breastfeeding to the baby. 5.The mother has no desire for to continue to intervene. 6.The neonates is transmitted to the neonatal unit 7. Apgar scores 1 and 5 minutes in neonates less than 7

Intervention groups

intervention group performs oketani breast massage and examines the mother's need support during lactation and successful breastfeeding. control group receives routine care and examines the mother's need support during lactation and successful breastfeeding.

Main outcome variables

breast massage, mother's need support during lactation, breastfeeding, neonates, cesarean

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190129042542N1**
Registration date: **2019-05-13, 1398/02/23**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-13, 1398/02/23**
Update count: **0**

Registration date

2019-05-13, 1398/02/23

Registrant information

Name

Maryam Mahdizadeh Shahri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-19, 1398/01/30

Expected recruitment end date
2019-08-21, 1398/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Breast Massage on the Mother's Need for support During Lactation and Successful Breastfeeding in Neonates born through Cesarean Section in the Selected Hospitals Affiliated to Shahid Beheshti University Medical Sciences 2019.

Public title
Evaluation of Breast Massage on the Mother's Need for support During Lactation and Successful Breastfeeding in Neonates born through Cesarean Section in the Selected Hospitals Affiliated to Shahid Beheshti University Medical Sciences 2019.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Single pregnancy Maternal aged 18 to 35 Physical and mental illness is not based on mother's statement and file documentation The gestational age is 37 to 41 weeks There is no history of breast surgery, breast cancer, burn and scarring in the breast There is not Prenatal illnesses, such as Gestational Diabetes(GDM), Preeclampsia, and viral diseases such as AIDS and Hepatitis. There is not Prenatal abnormalities such as Placental abruption, Placenta Previa, heart and respiratory diseases.
Exclusion criteria:
severe hemorrhage during cesarean section Uterine inertia and atony during cesarean section use any drugs that Suppression lactation The mother has no desire for breastfeeding to the baby. The mother has no desire for to continue to intervene. The neonates is transmitted to the neonatal unit Apgar scores 1 and 5 minutes in neonates less than 7
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, a suitable sampling method (selection among mothers of candidates for cesarean section) based on inclusion criteria, and random allocation in two groups of intervention and control by simple random method.
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 Shahid Beheshti University of Medical Sciences
Street address
in front of Shahid Rajaee Hospital,Intersection Hashemi Rafsanjani Hwy, Valiasr St, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2019-01-28, 1397/11/08
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1397.223

Health conditions studied

1

Description of health condition studied
Cesarean, Breast Massage, Lactation, Successful Breastfeeding, Neonates
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The first main variable in this study is successful breastfeeding
Timepoint
Time interval to measure the successful breast feeding variable, first breastfeeding and last one before discharge mother from hospital(22-28 hour after cesarean delivery).
Method of measurement
instrument to assess successful breastfeeding is IBFAT(Infant Breastfeeding Assessment Tool)

2

Description
The second main variable in this study is mother's need support during lactation.

Timepoint
Time interval to measure the mother's need support during lactation variable, first breastfeeding and last one before discharge mother from hospital(22-28 hour after cesarean delivery).

Method of measurement
instrument to assess mother's need support during lactation is LATCH(Breastfeeding Charting System and Documentation Tool).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Oketani breast massage included eight manual techniques performed within 60 sec and repeated for 15-20 min. Levels 1-3 of the given therapy were associated with the detachment of the bottom of the breast from its pectoralis major muscle. Furthermore, levels 4-6 involved pulling the whole breast with two thumbs down and to both sides by both hands. Additionally, level 7 included rotating the breast gently clockwise with stretching of its base, and level 8 was about milking the breast in four different directionsroup. This massage is done in two steps; first step before cesarean and the second in recovery after cesarean.

Category
Prevention

2

Description
Control group: receive routine care for the mothers in the control group and review Successful breastfeeding and mother's need support during lactation by IBFAT and LATCH tools.This review is done in two steps; first step during first breastfeeding after cesarean delivery and the second during the last breastfeeding before mom's discharged (The interval is 22 to 28 hours after cesarean delivery).

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Mahdiyeh Hospital

Full name of responsible person
Maryam Varzeshnejad

Street address
Shishehgarkhaneh Alley, Shahid Rajabnia Ave, Fadaiyan Eslam Blvd, Shosh Square

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2

Recruitment center

Name of recruitment center
Shohadaye Tajrish Hospital

Full name of responsible person
Parastoo Ojian

Street address
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3

Recruitment center

Name of recruitment center
Imam Hossein Hospital

Full name of responsible person
Mitra Zandi

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4

Recruitment center

Name of recruitment center
Taleqani Hospital

Full name of responsible person

Maryam Allah Bakhshian

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Next to Shahid Beheshti University of Medical Sciences, Shahid Arabi Ave, Chamran Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahrokh Dolatian

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Hashemi Rafsanjani Hwy, School Of Nursing and Midwifery

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http://sbmu.ac.ir/index.jsp?siteid=243

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Mahdizadeh Shahri

Position

Master of Science in Neonatal Intensive Care Unit

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Manijeh Nourian

Position

Doctor of Philosophy, Nursing Departement, Master of Science, Management of Pediatric Nursing

Latest degree

Ph.D.

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable