Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the Impact of Essential Newborn Care Guidelines on Breastfeeding Indicators and Neonatal Outcomes: A Randomized Controlled Trial

Protocol summary

Study aim
Determining the impact of the Essential Early Neonatal Care Guide on breastfeeding indicators and neonatal outcomes

Design
Randomized controlled trial with control group and parallel groups. Randomization with colored cards

Settings and conduct
Pregnant women who referes to Nohe Dey hospital of torbat heydariyeh city for vaginal delivery, if were eligible, include in the study and by using colored cards, randomly assign to intervention and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Willingness to participate in the study, Maternal age between 18-45 years, Gestational age 42-37 weeks, Vaginal delivery, Singleton pregnancy. Exclusion criteria: Mothers with medical and obstetric disorders, Mothers with contraindications to breastfeeding, Mothers with no intention of breastfeeding, Mothers with flat or inverted nipples

Intervention groups
Intervention group: a series of interventions for the infant began at birth and continued for 90 minutes after birth or until the first successful breastfeeding was completed on the mother's abdomen and chest. These included keeping the infant warm and dry, initiating early and continuous skin-to-skin contact, clamping and cutting the umbilical cord after the umbilical artery pulse had stopped, and guiding the mother to initiate the first breastfeeding as soon as she saw early signs of hunger. The control group also received routine hospital care.

Main outcome variables
Duration of first successful breastfeeding; infant behavior during first breastfeeding; breastfeeding self-efficacy; exclusive breastfeeding; time of lactogenesis II.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221206056724N2**
Registration date: **2026-04-10, 1405/01/21**
Registration timing: **registered_while_recruiting**

Last update: **2026-04-10, 1405/01/21**
Update count: **0**

Registration date
2026-04-10, 1405/01/21

Registrant information

Name
Yegane Lagzian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 938 784 8900

Email address
yegane.lagzian@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-03-06, 1404/12/15

Expected recruitment end date
2026-06-22, 1405/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the Impact of Essential Newborn Care Guidelines on Breastfeeding Indicators and Neonatal Outcomes: A Randomized Controlled Trial

Public title
Investigating the Impact of Newborn Care Guidelines on Breastfeeding Indicators

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in the study Mother's age between 18 and 45 years Gestational age 37 – 42 weeks Vaginal delivery Singleton pregnancy

Exclusion criteria:
Mothers with medical and obstetric disorders Mothers with contraindications to breastfeeding Mothers without intention to breastfeeding Mothers with flat or inverted nipples

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, a random assignment method using colored cards will be used to divide the research units into two groups: intervention and control. For this purpose, green cards (representing the intervention group) and red cards (representing the control group) will be prepared in equal numbers according to the final sample size and placed in dark, sealed, and opaque envelopes. After each mother meets the entry requirements for the study and obtains informed consent, an envelope will be randomly selected by one of the research assistants who is not involved in the grouping process. The color of the card inside the envelope will determine which group (intervention or control) the research unit will be placed in. This method will continue until the sample size is completed in both groups to ensure a random and balanced distribution of participants in the two groups.

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 Torbat Heydariyeh University of Medical Sciences

Street address
Mehr Boulevard, Valiasr Town

City
Torbat Heydariyeh

Province
Razavi Khorasan

Postal code
9516160061

Approval date
2026-02-10, 1404/11/21

Ethics committee reference number
IR.THUMS.REC.1404.057

Health conditions studied

1

Description of health condition studied
Breastfeeding Indicators

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Neonatal Outcomes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Baby's behavior at the beginning of breastfeeding

Timepoint
During the first breastfeeding after birth during the intervention

Method of measurement
Infant Breastfeeding Assessment Tool

2

Description
Breastfeeding self-efficacy

Timepoint
At the time of discharge after the intervention

Method of measurement
Breastfeeding Self-Efficacy Scale-Short Form

3

Description
Lactogenesis 2

Timepoint
The first time research units feel fullness and firmness in the breasts after giving birth after the intervention
Method of measurement
Lactogenesis 2 Assessment Checklist

4

Description
Exclusive breastfeeding
Timepoint
At the time of discharge after the intervention
Method of measurement
Exclusive breastfeeding assessment checklist

Secondary outcomes

1

Description
Neonatal temperature
Timepoint
At 15, 30, 45, 60, 75, 90, 105 and 120 minutes after birth
Method of measurement
mercury thermometer

2

Description
Neonatal arterial oxygen saturation
Timepoint
At 15, 30, 45, 60, 75, 90, 105 and 120 minutes after birth
Method of measurement
Pulse oximeter device

3

Description
Neonatal's heartbeat
Timepoint
At 15, 30, 45, 60, 75, 90, 105 and 120 minutes after birth
Method of measurement
Pulse oximeter device

Intervention groups

1

Description
Intervention group: A set of interventions initiated at the time of birth in accordance with WHO guidelines and continued for up to 90 minutes after birth or until the completion of the first successful breastfeeding on the mother’s abdomen and chest. These interventions include immediate drying and warming of the newborn on the mother’s abdomen, early and continuous skin-to-skin contact for 90 minutes or until the end of the first successful breastfeeding through the breast crawl method, clamping and cutting of the umbilical cord after cessation of pulsation in the umbilical artery, and guiding the mother to initiate the first breastfeeding via the breast crawl method upon observing early hunger cues.
Category
Prevention

2

Description
Control group: Routine ward care, including early clamping of the umbilical cord, skin-to-skin contact for 10 minutes, drying and warming of the newborn under a radiant warmer, and initiation of the first breastfeeding using the conventional method after completion of the third stage of labor and repair of episiotomy and/or any perineal lacerations.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
9 Dey Hospital of Torbat Heydariyeh University of Medical Sciences
Full name of responsible person
Yegane Lagzian
Street address
No 2, Gharani Ave., Gharani Blvd
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Postal code
9518813774
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+98 51 5222 6016
Email
yegane.lagzian@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Torbate-Heidaria University of Medical Sciences
Full name of responsible person
Seyed Mohammad Ahmadi Soleimani
Street address
Mehr Boulevard, Valiasr Town
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Torbat Heydariyeh
Province
Razavi Khorasan
Postal code
9516160061
Phone
+98 51 5242 1000
Email
Mostafaahmadi24@gmail.com
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Torbate-Heidaria 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
Torbate-Heidaria University of Medical Sciences
Full name of responsible person
Yegane Lagzian
Position
Faculty member of the Midwifery Department
Latest degree
Master
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The participants are coded to increase access to them and their information, but at the time of publication, only the result is published and the information of the participants is not published in any way
When the data will become available and for how long
6 months after the results are published
To whom data/document is available
Access is open to the public
Under which criteria data/document could be used
If people have a request, without mentioning the coding

and personal information of the people, only the main and secondary outcomes, will be provided to the requester.

From where data/document is obtainable

E-mail

What processes are involved for a request to access data/document

First, the applicant sends a message to the e-mail and explains the reason for using the data, and within a week, the information will be sent to the applicant with conditions and restrictions.

Comments