

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The Effect of Mother-Newborn Skin-to-skin Contact Education during first two months of newborn life on Exclusive Breastfeeding

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

The Effect of Mother-Newborn Skin-to-skin Contact Education during first two months of newborn life on Exclusive Breastfeeding

Last update: **2019-09-02, 1398/06/11**

Update count: **0**

Registration date

2019-09-02, 1398/06/11

Design

A randomized, controlled clinical trial with control group

Registrant information

Name

Leila Elmi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6651 2396

Email address

sadr.z@iums.ac.ir

Settings and conduct

The aim of this study was to investigate the effect of skin and skin contact between mother and baby on the success rate of exclusive breastfeeding, infant colic, reflux, and child growth in 3 to 5-day-old infants referred to the Valfajr Clinic. How to do skin-to-skin contact is that the mother is asked to bare her baby (diaper only) between her two bare breasts, at least 1 hour per day. The control group will not receive any training on the benefits of skin contact with the skin.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Entry criteria: Infants' mothers and infants within 3 to 5 days of age Mother tends to participate in the study. Mothers who have breastfed up to 3 to 5 days old. Exclusive criteria: Illiterate mothers, Mothers with conditions and illnesses that are contraindicated in breastfeeding. Infants with conditions and diseases that are contraindicated in lactation

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2019-10-22, 1398/07/30

Intervention groups

The mothers are in the intervention group is recommended skin-to-skin contact at least 60 minutes per day. The control group will not train on the benefits skin-to-skin contact.

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Exclusive breastfeeding

Trial completion date

empty

General information

Scientific title

The Effect of Mother-Newborn Skin-to-skin Contact Education during first two months of newborn life on Exclusive Breastfeeding

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190622043966N1**

Registration date: **2019-09-02, 1398/06/11**

Public title

Skin -to-Skin Contact Education

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
All Mother and Newborn in 3 to 5 day from life of newborn that refer to valfajre clinic

Exclusion criteria:
Illiterate mothers Mothers with conditions and disease that are contraindications to breastfeeding .Includes :Psychiatric disorders , substance abuse ,active infectious disease such as TB and AIDS ,and the use of drugs to prevent lactation such as chemotherapy drugs
Infants with conditions and disease that are contraindications to breastfeeding .includes :Cleft palate, Galactosemia , Phenylketonuria

Age
From **3 days** old to **5 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **135**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocking :At the beginning of the project , based on the random four - way blocking method , the pocket will be provided to the researcher , which at the beginning of each day will open one of them without disturbing , and the letter contained in the envelope will be based on the contract. The previous one will show that the patients will be in the intervention group(Skin -to -SKIN contact Education)that day , or in the control group.

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

Iranian Nationl Comitee for ethics in biomedical research

Street address

Dashegib Street, West of Tehran Health Center, Valfajr Clinic

City

Tehran

Province

Tehran

Postal code
1444643961

Approval date
2019-06-10, 1398/03/20

Ethics committee reference number
IR.IUMS.FMD.REC.1398.111

Health conditions studied

1

Description of health condition studied

Skin-to- skin contact and its effects on exclusive breastfeeding

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Exclusive Breastfeeding

Timepoint

3 to 5 days and end of first two months of life

Method of measurement

Self-declaration

Secondary outcomes

1

Description

Baby crying rate

Timepoint

3 to 5 days and end of first two months of life

Method of measurement

Self-declaration

2

Description

Baby Sleep Rates

Timepoint

3 to 5 days and end of first two months of life

Method of measurement

Self-declaration

3

Description

Quality of life for mothers

Timepoint

3 to 5 days and end of first two months of life

Method of measurement

SF-12 questionnaire

4

Description

Weight at 2 months

Timepoint

3 to 5 days and end of first two months of life

Method of measurement

Digital scales

5**Description**

Height at 2 months

Timepoint

3 to 5 days and end of first two months of life

Method of measurement

Height gauge

6**Description**

Head circumcision

Timepoint

3 to 5 days and end of first two months of life

Method of measurement

centimeter

Intervention groups**1****Description**

Intervention group: Maternal and infant Skin -to- Skin contact Education during the first two months of life at least 1 hour per day in two first months

Category

N/A

2**Description**

Control group:no training in the field of benefit skin-to-skin contact

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

valfajr clinic

Full name of responsible person

Leila Elmi

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Email

elmi12leila@yahoo.com

Web page address

http://cio.iums.ac.ir/

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr.Sadr

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

leila Elmi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Family Physician

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Sadr

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Elmi Leila

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Family Physician

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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

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