Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of father's education and participation on the success rate of breastfeeding in mothers with preterm infant

Protocol summary

Study aim
Determine of the effect of father's education and participation on the success rate of breastfeeding in mothers with preterm infant

Design
Clinical trial with control group, with parallel groups, three blind, randomized

Settings and conduct
In this study, mothers with preterm infants with less than 37 weeks of gestational age at Imam Reza Hospital of Kermanshah are examined. Infants are randomly divided into two groups: intervention and control. In the intervention group, fathers receive three-session training on breastfeeding and infant feeding while in the control group only routine training is performed. The study is a three-blind study which both mothers and both the assessor and the analyst are not aware of the allocation of groups.

Participants/Inclusion and exclusion criteria
gestational age less than 37 week; non of asphyxia during infant's birth; non of heart problems and serious congenital anomalies; do not use hypnotic drugs by infant; non of congenital malformation and abnormalities in the jaw and mouth

Intervention groups
In the intervention group, infant' s fathers will be taught three face-to-face sessions on infant nutrition, lactation problems, and breastfeeding benefits. At the end of the session, a leaflet with the main points of the session was provided to the fathers. In the control group, training sessions were not provided and only routine training was given to fathers.

Main outcome variables
The frequency of breastfeeding; the number of correct breastfeeding; the success rate of the mother in breastfeeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151220025619N3**
Registration date: **2018-03-16, 1396/12/25**
Registration timing: **prospective**

Last update: **2018-03-16, 1396/12/25**
Update count: **0**

Registration date
2018-03-16, 1396/12/25

Registrant information

Name
Leila Mohammadi Pirkashani

Name of organization / entity
Esfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-21, 1397/02/01

Expected recruitment end date
2018-09-23, 1397/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of father's education and participation on the success rate of breastfeeding in mothers with preterm infant

Public title
The effect of father's education and participation on the success rate of breastfeeding in mothers with preterm infant

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
gestational age less than 37 week

Exclusion criteria:
Asphyxia during infant's birth Heart problems and serious congenital malformations of the infant Use hypnotic drugs Congenital malformation and abnormalities in the jaw and mouth

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the newborns were randomly assigned to two random groups using a random number table. A random numbered table is a collection of numbers that are generated without a specific pattern or order and in a completely random manner. To use the random number table, the researcher must first determine the number of the table to read (for example: up, down, left or right), the second assumption is that the researchers will consider the numbers for different groups, in this study paired numbers will be assigned to the intervention group in the random numbers table and the individual numbers will be assigned to the control group.

Blinding (investigator's opinion)
Triple blinded

Blinding description
For blinding, for mothers not to understand, the fathers of both groups are trained, The difference is that the fathers of the control group receive only routine training. The evaluator, also helping the researcher, is not aware of the allocation of the groups and the analyst is not aware of the allocation of groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

Street address
Imam Reza Hospital., Nurse Blvd

City
Kermanshah

Province
Kermanshah

Postal code
6715838316

Approval date
2018-02-28, 1396/12/09

Ethics committee reference number
IR.KUMS.REC.1396.692

Health conditions studied

1

Description of health condition studied
Breastfeeding in mothers with preterm infant

ICD-10 code
O92.7

ICD-10 code description
Other and unspecified disorders of lactation

Primary outcomes

1

Description
The success rate of breastfeeding in mothers with preterm infants

Timepoint
End one month, three months and six months

Method of measurement
Researcher made questionnaire

Secondary outcomes

1

Description
Maternal Satisfaction Score from Breastfeeding

Timepoint
6 months

Method of measurement
Researcher made questionnaire

Intervention groups

1

Description

Intervention group: The fathers of the intervention group were interviewed and offered a face-to-face, 40-minute session about infant feeding and the difficulties sometimes associated with breastfeeding, such as fear of milk insufficiency; hand expression breast milk; teaching of feeding methods in preterm infants such as feeding by cup; return to outside employment in working mothers; and problems such as breast engorgement, mastitis, sore and inverted nipples or flat nipples and breast refusal. They were taught how problems with lactation can occur and how it is possible to prevent and manage them. Moreover, attention was paid to the concerns that a father might have in relation to breastfeeding, and the fathers were helped to recognize and accept their unique and vital role in the success of breastfeeding especially in mothers with preterm infants. At the end of the session, a leaflet with the main points of the session was provided to the fathers. The nurse who conducted the intervention was trained through the training course.

Category

Behavior

2

Description

Control group: In the control group, training sessions were not provided and only routine training was given to fathers.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital Kermanshah

Full name of responsible person

Leila Mohammadi Pirkashani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research of Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farid Najafi

Street address

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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

Deputy of Research of Kermanshah University of Medical Sciences

Proportion provided by this source

5

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

Kermanshah University of Medical Sciences

Full name of responsible person

Leila Mohammadi Pirkashani

Position

Master of Science in Neonatal Intensive Care Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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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)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available