

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Effect of planned breastfeeding education to mothers versus control group on the weight gaining in low birth weight newborns: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of planned breastfeeding education to mothers versus control group on the weight gaining in low birth weight newborns

Design

This is a randomized clinical trial with control group, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct

This study will be performed in the Fatemieh Hospital in Hamadan city on 40 eligible pregnant women. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 1 to 29 days; Birth weight between 1500 to 2499 gr; Literate mother; Exclusion criteria: Multiple twins; Mother addiction; Congenital malformations Pregnancy or breastfeeding

Intervention groups

Intervention group: Routine care of mother and child during breastfeeding in addition to five 20-minute sessions planned breastfeeding education at intervals after delivery, 24 hours after delivery, and days 5, 15, and 60 postpartum, including how to properly hug the baby, to the breast infant placement, signs of effective sucking, benefits of exclusive breastfeeding, frequent feeding of the baby around the clock, duration of feeding the baby, avoiding the use of glass, proper milking method, providing a manual Control group: Routine care of mother and child during breastfeeding

Main outcome variables

Primary outcome: Measuring birth weight

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N421**

Registration date: **2022-04-14, 1401/01/25**

Registration timing: **retrospective**

Last update: **2022-04-14, 1401/01/25**

Update count: **0**

Registration date

2022-04-14, 1401/01/25

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of planned breastfeeding education to mothers versus control group on the weight gaining in low birth weight newborns: a randomized clinical trial

Public title

Effect of planned breastfeeding education to mothers versus control group on the weight gaining in low birth weight newborns

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 1 to 29 days; Birth weight between 1500 to 2499 gr; Literate mother;

Exclusion criteria:

Multiple twins; Mother addiction; Congenital malformations Pregnancy or breastfeeding

Age

From **1 day** old to **29 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2015-11-24, 1394/09/03

Ethics committee reference number

IR.UMSHA.REC.1394.335

Health conditions studied

1

Description of health condition studied

Low birth weight

ICD-10 code

P07.1

ICD-10 code description

Other low birth weight newborn

Primary outcomes

1

Description

Measuring birth weight

Timepoint

On 1, 15 , 60 days after birth

Method of measurement

Using standard scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine care of mother and child during breastfeeding in addition to five 20-minute sessions planned breastfeeding education at intervals after delivery, 24 hours after delivery, and days 5, 15, and 60 postpartum, including how to properly hug the baby, to the breast infant placement, signs of effective sucking, benefits of exclusive breastfeeding, frequent feeding of the baby around the clock, duration of feeding the baby, avoiding the use of glass, proper milking method, providing a manual

Category

Treatment - Other

2

Description

Control group: Routine care of mother and child during breastfeeding

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan city

Full name of responsible person

Sahar Rahmani

Street address

Fatemieh Hospital, Pasdaran Ave.

City

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Province

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6517838695

Phone

+98 81 3828 3939

Email

sahar.r70a@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Sahar Rahmani

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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sahar.r70a@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Roya Amini

Position

Master of Community Health

Latest degree

Master

Other areas of specialty/work

Public Health/Community Medicine

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Email

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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