

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison between the effect of skin to skin contact mother and newborn and routine care on temperature and breastfeeding successfulness in full term newborns after cesarean delivery.

Protocol summary

Summary

The aim of this randomized clinical trial is to determine and compare the temperature of mothers and newborns after cesarean delivery in two groups of skin to skin contact and routine care. For this purpose, eighty eight pairs of non emergency cesarean delivery mothers and term newborns with Apgar score more than seven will be selected and placed randomly in two groups of skin to skin contact (Forty four pairs of mothers and newborns) and routine care (Forty four pairs of mothers and newborns). In the skin to skin contact group, after surgery and transferring the mother to the ward, skin to skin contact will be done for one hour between the mother and the newborn. In the routine care group, according to hospital usual method, the newborn will be handed to the mother. The newborns' temperatures in both groups will be measured in the operating room immediately after birth, in nursery ward, when being handed to the mother and every half hour for one hour with infrared ray thermometer on the forehead. Also, the mothers' temperatures will be measured before and after the surgery, when being returned to the ward and every half hour for one hour with the same kind of thermometer. During this time, the mothers will be trained on how to breastfeed their newborns. The data collection tool is a questionnaire which includes four parts: (Demographic data, temperature record form of mothers and newborns, infant breastfeeding assessment tool and mothers satisfaction with the skin to skin contact care).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110037697N1**
Registration date: **2012-09-16, 1391/06/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-09-16, 1391/06/26

Registrant information

Name

Shourangiz Beiranvand

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 1330 5313

Email address

shorangiz.beiranvand@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Lorestan University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2012-11-21, 1391/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the effect of skin to skin contact mother and newborn and routine care on temperature

and breastfeeding successfulness in full term newborns after cesarean delivery.

Public title

The effect of skin to skin contact mother and newborn on temperature and breastfeeding in newborns after cesarean delivery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria for mothers: Age of 18-36 years old, singleton pregnancy, non - emergency cesarean delivery with spinal anesthesia and gestational age of 38-42 weeks. Inclusion criteria for newborns: Full term, Maximum age of newborns 4 hours after birth (One - day newborn), newborns' birth weight of more than 2500 gram and first and fifth minute Apgar score of more than seven. Exclusion criteria for mothers: Any medical problems in mothers after surgery Exclusion criteria for newborns: Any medical problems in newborns which can disrupt skin to skin contact and breastfeeding

Age

From **1 year** old to **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization will be done by using of random numbers table and closed envelopes.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

Department of Research and Technology, Lorestan University of Medical Sciences, Kamalvand

City

Khorramabad

Postal code

381351698

Approval date

2012-05-12, 1391/02/23

Ethics committee reference number

66375/200

Health conditions studied

1

Description of health condition studied

Temperature of newborn

ICD-10 code

P80.8

ICD-10 code description

Other hypothermia of newborn

2

Description of health condition studied

Breastfeeding

ICD-10 code

P92.5

ICD-10 code description

Neonatal difficulty in feeding at breast

Primary outcomes

1

Description

Temperature of Newborns

Timepoint

Before and immediately after intervention and every half hour for one hour during intervention

Method of measurement

Infrared ray thermometer on the forehead, IN4 model

2

Description

Infants' breastfeeding status

Timepoint

During intervention for one hour

Method of measurement

Standard questionnaire of the Infant Breastfeeding Assessment Tool (IBAT)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After the mother's cesarean delivery and her transfer to the ward, the naked newborn, in prone position, will be placed between the mother's breasts for skin to skin contact with her. To avoid heat

wastage, the newborn's head will be covered with a hat and his / her back will be covered with a blanket. The mother's and newborn's temperatures will be measured immediately after skin to skin contact and every half hour for one hour with IN4 model infrared ray thermometer on the forehead. Also, Infant Breastfeeding Assessment Tool (IBAT) will be used to measure infants' success in breastfeeding; which includes four subscales: Readiness to feed, rooting reflex, latching on to the breast and sucking reflex. Each subscale has 0-3 scores and the total score ranges from 0-12.

Category

Prevention

2

Description

Control group: After the mother's cesarean delivery and her transfer to the ward, the dressed newborn will be placed in the bassinet or in the mother's bed as a hospital usual method. The mother's and newborn's temperatures will be measured when newborn handed to her mother and every half hour for one hour with IN4 model infrared ray thermometer on the forehead. Also, Infant Breastfeeding Assessment Tool (IBAT) will be used to measure infants' success in breastfeeding; which includes four subscales: Readiness to feed, rooting reflex, latching on to the breast and sucking reflex. Each subscale has 0-3 scores and the total score ranges from 0-12.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Asali Hospital related to Lorestan University of Medical Sciences

Full name of responsible person

Shourangiz Beiranvand

Street address

Nursing Department, Nursing and Midwifery Faculty, Lorestan University of Medical Sciences, Kamalvand

City

Khorramabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Lorestan University of Medical Sciences

Full name of responsible person

Mohammad Hassan Kaedi

Street address

Vice Chancellor for Research, Lorestan University of Medical Sciences, Kamalvand

City

Khorramabad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research of Lorestan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Lorestan University of Medical Sciences

Full name of responsible person

Shourangiz Beiranvand

Position

Master of nursing, Faculty member of Lorestan University of Medical Sciences

Other areas of specialty/work

Street address

Nursing Department, Nursing and Midwifery Faculty, Lorestan University of Medical Sciences, Kamalvand

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381351698

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+98 66 1620 0140

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Email

shorangizbiranvand@yahoo.com;
shorangiz.beiranvand@lums.ac.ir

Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty