

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of companion and midwife presence during the mother-and-baby skin-to-skin contact on pain and maternal anxiety and neonate physiological indices

Protocol summary

Study aim

Comparison of the effect of companion and midwife presence during SSC on pain and maternal anxiety and neonatal physiological indices

Design

A randomized clinical trial, Randomization using quadratic randomized blocks, sample size= 92

Settings and conduct

This study will be conducted in the maternity ward of AmiralMomenin Hospital in Zabol. In both groups, immediately after birth, the baby will be placed on the maternal abdomen, and dried, and the Apgar scores will be determined. If conditions will be appropriate for the skin-to-skin contact (SSC), the cord will be cut off after 3 minutes, and the head and back should be covered with a warm towel. The infant's axillary temperature, the saturation pressure oxygen (SPo2), and the heart rate (HR) will be measured using a mercury thermometer and a pulse oximeter, respectively. The maternal pain and anxiety will be evaluated on a visual analog scale, then, SSC is uninterrupted, and the baby will be placed on the mom's chest, (Baby's head between breasts) and then SSC will begin. This contact will continue for at least one hour. The infant care midwife and the mothers' companion will perform SSC in both control and intervention groups, respectively, while the researcher (midwife) will be present in both groups and will monitor the work process. Neonatal physiological indices, maternal pain, and anxiety will be measured at 30, 60, and 90 minutes after the beginning of SSC.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Natural childbirth, No medical problems and abnormality in the infant Exclusion criteria: Any factor that prevents skin contact.

Intervention groups

In this study, the samples will be equally divided into two groups of maternal and neonatal SSC with a companion

(intervention) and midwife (control) presence

Main outcome variables

Infant temperature; Infant HR; SPo2; maternal pain; maternal anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200120046200N2**

Registration date: **2020-05-12, 1399/02/23**

Registration timing: **prospective**

Last update: **2020-05-12, 1399/02/23**

Update count: **0**

Registration date

2020-05-12, 1399/02/23

Registrant information

Name

Seyedeh saeedeh Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4365 1807

Email address

mousavi.ss@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of companion and midwife presence during the mother-and-baby skin-to-skin contact on pain and maternal anxiety and neonate physiological indices

Public title
Comparison of the effect of companion and midwife presence during the mother-and-baby skin-to-skin contact

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Single pregnancy and wanted pregnancy Natural delivery Lack of obstetrics complications (such as gestational hypertension, gestational diabetes, prolonged or suspended labor, and fetal distress) No history of maternal medical diseases or mental illnesses Birth weight ≥ 2500 One minute Apgar score ≥ 7 No medical problem and abnormality in the baby Gestational age ≥ 37 weeks No manual removal of placenta No analgesia during labor No prohibition of breastfeeding Having a lady companion
Exclusion criteria:
 Maternal unwillingness to participate in the research Third-or fourth-degree perineal lacerations Postpartum hemorrhage Five minute Apgar score < 7 Anything interrupting skin-to-skin contact

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **92**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation for placement in the intervention and control group is done by random block method in four blocks and with allocation software: In this way, by entering the research units in the plan, by referring to the four blocks (letter A belongs to the intervention group and letter B belongs to the control group), the research units are assigned to the intervention and control 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 Iran University of Medical Sciences
Street address
 Fifth floor, Headquarters., Iran University of Medical Sciences., Hemmat Highway between Chamran and Sheikh Fazlullah
City
 Tehran
Province
 Tehran
Postal code
 ۱۴۴۹۶۱۴۵۳۵
Approval date
 2020-03-15, 1398/12/25
Ethics committee reference number
 IR.IUMS.REC.1398.1364

Health conditions studied

1

Description of health condition studied
 Maternal pain and anxiety and assessment of neonatal physiological parameters
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
 Mother's pain
Timepoint
 Before intervention, 30, 60 and 90 minutes after beginning skin to skin contact
Method of measurement
 Visual Analogue Scale (VAS)

2

Description
 Infant temperature
Timepoint
 Before intervention, 30, 60 and 90 minutes after beginning skin to skin contact
Method of measurement
 Mercury thermometer

3

Description

Infant heart rate

Timepoint

Before intervention, 30, 60 and 90 minutes after beginning skin to skin contact

Method of measurement

Pulse Oximeter device

4

Description

Percentage of oxygen saturation of the infant's blood

Timepoint

Before intervention, 30, 60 and 90 minutes after beginning skin to skin contact

Method of measurement

Pulse Oximeter device

5

Description

Mother's anxiety

Timepoint

Before intervention, 30, 60 and 90 minutes after beginning skin to skin contact

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Immediately after birth, the baby will be placed on the maternal abdomen, and dried, and the Apgar scores will be determined. If conditions will be appropriate for the skin-to-skin contact (SSC), the cord will be cut off after 3 minutes, and the head and back should be covered with a warm towel. The infant's axillary temperature, the saturation pressure oxygen (SPo2), and the heart rate (HR) will be measured using a mercury thermometer and a pulse oximeter, respectively. The maternal pain and anxiety will be evaluated on a visual analog scale, then, SSC is uninterrupted, and the baby will be placed on the mom's chest, (Baby's head between breasts), and then SSC will begin. This contact will continue at least one hour. In the intervention group, the mother's companion will perform SSC, while the researcher (midwife) will be present and will monitor the work process. The infant's axillary temperature, blood oxygen saturation percentage, infant heart rate, pain and maternal anxiety will be measured at 30, 60 and 90 minutes after the onset of skin contact.

Category

Rehabilitation

2

Description

Control group: Immediately after birth, the baby will be placed on the maternal abdomen, and dried, and the Apgar scores will be determined. If conditions will be appropriate for the skin-to-skin contact (SSC), the cord will be cut off after 3 minutes, and the head and back should be covered with a warm towel. The infant's axillary temperature, the saturation pressure oxygen (SPo2), and the heart rate (HR) will be measured using a mercury thermometer and a pulse oximeter, respectively. The maternal pain and anxiety will be evaluated on a visual analog scale, then, SSC is uninterrupted, and the baby will be placed on the mom's chest, (Baby's head between breasts), and then SSC will begin. This contact will continue for at least one hour. In this group, a midwife does skin contact. The infant's axillary temperature, blood oxygen saturation percentage, infant heart rate, pain and maternal anxiety will be measured at 30, 60 and 90 minutes after the onset of skin contact.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Amirmomenin Hospital

Full name of responsible person

Fateme Harati Kabir

Street address

Ali Amirmomenin Hospital., 3Km; Zabol Road - Zahedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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
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Position
 Assistant Professor
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Person responsible for updating data

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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