Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of immediate and routine kangaroo mother care on the outcomes and physiological indicators of premature babies hospitalized in the neonatal intensive care unit

Protocol summary

Study aim

To compare the effects of immediate kangaroo care and routine kangaroo care on adverse clinical outcomes and physiological parameters among preterm infants admitted to the neonatal intensive care unit of Hajar Hospital, Shahrekord.

Design

This study is a randomized, two-arm, parallel-group, non-blinded clinical trial conducted on 52 premature infants who will be randomly assigned to the intervention or control group using a block method.

Settings and conduct

This randomized controlled trial will be conducted in the NICU of Hajar Hospital, Shahrekord. A total of 52 preterm neonates (<37 weeks gestational age) will be randomly assigned to immediate or routine kangaroo mother care. Physiological indicators and adverse outcomes will be assessed during hospitalization and compared between groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Gestational age of 26–37 weeks, Absence of major congenital anomalies, Initiation of the intervention within the first 24 hours after birth, Stable respiratory status and written parental informed consent. Exclusion Criteria: Increased ventilatory support or hemodynamic instability, Severe respiratory distress or need for surgery, Withdrawal of parental consent, Infant death, discharge, transfer, or inability to complete follow-up.

Intervention groups

Intervention group: Preterm infants will receive early skin-to-skin contact with their mothers within 10 minutes to 24 hours after birth. The infant will be placed directly on the mother's chest to establish continuous skin-to-skin contact. Control group: Preterm infants will receive skin-to-skin care after stabilization of physiological status, typically initiated approximately 3 days after birth, according to routine clinical practice.

Main outcome variables

1. Respiratory rate 2. Arterial oxygen saturation (SpO_2) 3. Blood sugar 4. Time to full nutrition 5. Time to ideal weight

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251121068065N10**
Registration date: **2026-06-30, 1405/04/09**
Registration timing: **prospective**

Last update: **2026-06-30, 1405/04/09**
Update count: **0**

Registration date

2026-06-30, 1405/04/09

Registrant information

Name

kavoushgaran kavoushgaran

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

atiye.hesary@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-01, 1405/04/10

Expected recruitment end date

2026-09-25, 1405/07/03

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of immediate and routine kangaroo mother care on the outcomes and physiological indicators of premature babies hospitalized in the neonatal intensive care unit

Public title
Comparison of the effect of immediate and routine kangaroo mother care on the outcomes and physiological indicators of premature babies hospitalized in the neonatal intensive care unit
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Gestational age minimum 26 weeks and maximum 37 weeks. Absence of major congenital anomalies (e.g., diaphragmatic hernia, gastroschisis, omphalocele, or meningomyelocele). Initiation of the intervention within the first 24 hours after birth. Stable respiratory status with no increase in ventilator settings during the 6 hours preceding the intervention. Written informed consent obtained from parents or legal guardians. No active bleeding. Absence of a central venous catheter, peripherally inserted central catheter (PICC), chest tube, or umbilical arterial catheter. Singleton or twin birth.
Exclusion criteria:
Requirement for increased ventilator support during the study period. Withdrawal of parental consent. Hemodynamic instability requiring pharmacological intervention. Severe respiratory distress. Infant death during the study period. Requirement for surgical intervention. Discharge from the neonatal unit before completion of the study. Transfer to another healthcare facility or inability to complete follow-up assessments.
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
Stratified block randomization will be performed according to gestational age, with participants stratified into two categories (≤32 weeks and 33–37 weeks of gestation). Within each stratum, participants will be randomly allocated to the intervention or control group using permuted blocks of sizes 4 and 6 with a 1:1 allocation ratio. Allocation concealment will be ensured through sequentially numbered, sealed, opaque envelopes that are opened only after participant enrollment. Blocks will be filled progressively within each stratum until the required sample size of 52 participants is achieved, ensuring balanced allocation between study 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
Research Ethics Committee of Shahrekord and Borujen Faculties of Nursing and Midwifery and School of
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Building No. 2, University Headquarters, Kashani Boulevard, Shahrekord, Iran.
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Approval date
2026-05-17, 1405/02/27
Ethics committee reference number
IR.SKUMS.NUMHE.REC.1405.014

Health conditions studied

1

Description of health condition studied
The effect of kangaroo care on adverse outcomes and physiological indicators of premature infants
ICD-10 code
P07.3
ICD-10 code description
Preterm [premature] newborn [other]

Primary outcomes

1

Description
1. Respiratory rate
Timepoint
Respiratory rate in both groups is assessed 15 minutes

before the start of the intervention and 15 minutes after its initiation, and is continuously monitored throughout the hospitalization period.

Method of measurement

Respiratory rate is measured manually over one full minute using a stopwatch (Digikala43hs, China).

2

Description

2. Arterial oxygen saturation (SpO_2)

Timepoint

Arterial oxygen saturation (SpO_2) in both groups is assessed 15 minutes before the start of the intervention and 15 minutes after its initiation, and is continuously monitored throughout the hospitalization period.

Method of measurement

Arterial oxygen saturation is measured using a standard patient monitoring system (ARDP Sect Cardia 10, Sa Iran Company).

3

Description

3. Blood sugar

Timepoint

Blood sugar in both groups is assessed 15 minutes before the start of the intervention and 15 minutes after its initiation, and is continuously monitored throughout the hospitalization period.

Method of measurement

Blood glucose is measured using a glucometer (eBsensor, Taiwan) via heel-prick sampling once per shift due to its invasive nature.

4

Description

4. Time to full nutrition

Timepoint

The time of initiation of oral or breast milk feeding will be recorded after birth. From the start of feeding, infants will be followed continuously during NICU hospitalization until full enteral feeding is achieved.

Method of measurement

Nutritional status and attainment of full feeding will be assessed based on gestational age–specific criteria. In infants with gestational age <32 weeks, full feeding is defined as achieving an enteral intake of 150 mL/kg/day. In infants with gestational age 32–37 weeks, attainment of exclusive breastfeeding (BF) is considered as optimal nutrition.

5

Description

5. Time to ideal weight

Timepoint

Weight is measured daily.

Method of measurement

Body weight is measured daily at 9 PM using a digital scale (Taiwan-made, accuracy ±5 g). Measurements are performed with the infant wearing a dry diaper and no clothing. The weight of the diaper is measured separately and subtracted from the total weight to obtain the net body weight.

Secondary outcomes

1

Description

Sepsis

Timepoint

Sepsis will be assessed throughout the hospitalization period, from initiation of the intervention until discharge from the neonatal intensive care unit (NICU) or death of the infant, whichever occurs first.

Method of measurement

Sepsis will be diagnosed according to the standard neonatal sepsis criteria routinely used in the neonatal intensive care unit. Diagnosis will be based on the presence of clinical signs documented in the medical record and confirmation by a positive blood culture (BACTEC), as determined by the attending neonatologist. The outcome will be recorded as a dichotomous variable (yes/no).

2

Description

Intracerebral hemorrhage

Timepoint

Intracranial hemorrhage will be assessed from the initiation of the intervention until discharge from the neonatal intensive care unit or death of the infant, whichever occurs first.

Method of measurement

Intracranial hemorrhage will be diagnosed based on cranial ultrasonography findings indicating bleeding within the brain and confirmed by a neonatologist. The diagnosis will be documented in the patient's medical record and recorded as a dichotomous variable (yes/no).

3

Description

Necrotizing enterocolitis (NEC)

Timepoint

Necrotizing enterocolitis will be assessed daily from the initiation of the intervention until discharge from the neonatal intensive care unit.

Method of measurement

Diagnosis based on clinical symptoms and diagnostic findings recorded in the patient's chart including abdominal distension, feeding intolerance, gastric lavage, and diagnosis by a neonatologist. The variable is recorded qualitatively (yes/no). Recording tools include feeding form, lavage form, and abdominal circumference measurement.

4

Description

Neonatal death

Timepoint

Neonatal mortality will be assessed daily from the initiation of the intervention until discharge from the neonatal intensive care unit (NICU) or death of the infant, whichever occurs first.

Method of measurement

Neonatal mortality will be determined based on documented death during the hospitalization period and recorded as a dichotomous outcome (yes/no).

Intervention groups

1

Description

Control group (Routine Kangaroo Care): Preterm infants will receive skin-to-skin care after stabilization of physiological status, typically initiated approximately 3 days after birth, according to routine clinical practice. In this method, the mother is positioned in a semi-upright sitting posture on a kangaroo mother care (KMC) chair. The infant, wearing only a diaper and a cap, is placed in an upright position—commonly referred to as the “frog position”—on the mother’s chest between the breasts to ensure direct skin-to-skin contact.

Category

Treatment - Other

2

Description

Intervention group (Immediate Kangaroo Care): Preterm infants will receive early skin-to-skin contact with their mothers within 10 minutes to 24 hours after birth. The infant will be placed directly on the mother’s chest to establish continuous skin-to-skin contact.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Neonatal Intensive Care Unit, Hajar Hospital

Full name of responsible person

Dr. Nasser Khosravi

Street address

Hajar Hospital, Parastar Street, Kashani Boulevard, Shahrekord, Chaharmahal and Bakhtiari Province, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord 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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Senior student

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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