Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of abdominal massage combined with kangaroo mother care on digestive consequences, weight gain and serum bilirubin level In premature infants hospitalized in the neonatal intensive care unit

Protocol summary

Study aim

Effect of abdominal massage combined with kangaroo mother care on digestive consequences, weight gain and serum bilirubin level In premature infants hospitalized in the neonatal intensive care unit

Design

Clinical trial with a control group, with parallel groups, randomized on 60 patients. Sealed Envelope software will be used for randomization. There is no possibility of blinding in this study.

Settings and conduct

This study will be conducted in Sina Rezaie hospital in Arak. After the intervention of infants of each group in terms of weight gain, serum bilirubin levels and gastrointestinal consequences will be evaluated. There is no possibility of blinding in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No underlying congenital and infectious disease, Birth weight less than 2,500 grams, Born to non-addicted mothers with a gestational age of 28 to 36 weeks؛ Exclusion criteria: Infant parents' unwillingness to participate in the study, Infants with severe respiratory distress during the study, Deterioration of the baby's condition

Intervention groups

Control group: This group will receive only routine ward care, including kangaroo care by the mother. In this care, the infant is placed in a calm environment, naked and lying on the stomach between the bare breasts of the mother vertically. The infant's hips and arms should be bent. The infant's stomach should not be contracted. This care will be provided by the mother for 7 consecutive days, 3 times a day and for 1 hour each time.

Intervention group: In this group, the infant also receives abdominal massage in addition to the kangaroo care, in a way that the massage is performed for 7 consecutive days using "Version" olive oil made in Iran, 2 times a day, 15 minutes each time. The massage is performed in the "I love U" method.

Main outcome variables

Weight gain, serum bilirubin and gastrointestinal outcomes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210501051142N10**
Registration date: **2024-10-30, 1403/08/09**
Registration timing: **prospective**

Last update: **2024-10-30, 1403/08/09**
Update count: **0**

Registration date

2024-10-30, 1403/08/09

Registrant information

Name

Aida Arjloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3402 0115

Email address

golmehrsherafati@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-02, 1403/08/12

Expected recruitment end date

2025-01-01, 1403/10/12

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

Scientific title
Effect of abdominal massage combined with kangaroo mother care on digestive consequences, weight gain and serum bilirubin level In premature infants hospitalized in the neonatal intensive care unit

Public title
Effect of abdominal massage combined with mother kangaroo care on digestive consequences, weight gain and serum bilirubin level In premature infants
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
No underlying congenital and infectious disease Birth weight less than 2,500 grams Born to non-addicted mothers with a gestational age of 28 to 36 weeks With a nasogastric tube Exclusive breastfeeding
Exclusion criteria:
Infant parents' unwillingness to participate in the study Infants with severe respiratory distress during the study Deterioration of the infant condition
Age
From **1 day** old to **21 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Infants are assigned to groups in the order of arrival and based on the randomization sequence that will be generated in advance that this sequence is unpredictable and has no specific pattern and its arrangement is completely random. To assign the samples to two groups, the block randomization method will be used with a block size of 4, so that by using the random number generation software in the block method, the randomization sequence will be produced according to the required sample size for the two groups. First, all the states where two letters A and B can be arranged together in a block of 2 are created then a block is randomly selected by placing it between the blocks and from the arrangement pattern in that block for infants allocation is used then this block will be placed in the main container and another block will be selected again. All this will be done with software called Sealed Envelope. With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups that the researcher will not be able to predict which group the next person will be in.
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 Arak university of medical sciences
Street address
Arak university of medical sciences, Basij Sq., Sardasht region
City
Arak
Province
Markazi
Postal code
3848176593
Approval date
2024-09-08, 1403/06/18
Ethics committee reference number
IR.ARAKMU.REC.1403.173

Health conditions studied

1

Description of health condition studied
Premature infant
ICD-10 code
P07.3
ICD-10 code description
Preterm [premature] newborn [other]

Primary outcomes

1

Description
The rate of weight gain
Timepoint
Every 24 hours
Method of measurement
Weight gain in this study means the difference in the infant's weight from the start of the study to the last day of the intervention which will be measured once a day, according to the ward routine , by the researcher using the SECA scale, model 334-1321008, made in China. .

2

Description
The residual volume of the stomach
Timepoint
8 times a day before each meal
Method of measurement
The amount of liquid remaining in the stomach before eating a new portion of milk is lavaged by the researcher with a syringe with a volume of 5 cc in order to check the amount of digestion of the previous meal.

3

Description
Defecation
Timepoint
8 times a day before each meal
Method of measurement
In this study, defecation is the number of stools, which can be solid, semi-solid or liquid, reported by the infant's mother before each meal.

4

Description
Vomiting
Timepoint
8 times a day before each meal
Method of measurement
Vomiting in this study means the number of times vomiting after drinking milk, which will be recorded by the infant's mother in the gastrointestinal outcomes checklist.

5

Description
Abdominal Distention
Timepoint
Every 24 hours
Method of measurement
A change of more than 1.5 cm in the size of the abdomen with or without a feeling of bloating, which was measured by the researcher using a meter and will be recorded in the digestive outcomes checklist.

6

Description
Bilirubin Level
Timepoint
Every 24 hours
Method of measurement
The infant's bilirubin is taken by capillary inside the capillary tube and sent to the hospital laboratory and measured by photometric method according to the routine of the newborn department and is continuously collected and recorded in the form.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: This group will only receive routine ward care, including kangaroo care by the mother. Kangaroo care is taught to mothers by nurses. First, the infant is placed in a quiet and calm environment, naked and in a lying position on the stomach between the mother's breasts vertically, so that skin-to-skin contact is established between the mother and the baby. The infant's airway should be checked. The infant's hips should be bent in the "frog" position. The infant's arms should also be bent. The infant's stomach should not be contracted, so the baby has enough room for abdominal breathing. Care will be provided by the mother for 7 consecutive days, 3 times a day (according to ward routine) and each time for 1 hour. The feeding protocol and physical conditions of the environment will be the same for all premature babies. During the study, the newborns will be evaluated by the researcher in terms of weight gain, serum bilirubin level and digestive outcomes, including the residual volume of the stomach, the number of bowel movements, the number of vomiting and abdominal distension.
Category
Other

2

Description
Intervention group: In this group, in addition to receiving Kangaroo care, the infant also receives abdominal massage. The massage will be performed by the researcher for 7 consecutive days using "Version" baby olive oil, made in Iran, 2 times a day (Once between 9 and 11 in the morning and the second time between 9 and 11 at night) and each time for 15 minutes. During the intervention period, the feeding protocol and physical conditions of the environment will be the same for all premature infant. Abdominal massage will be done slowly and rhythmically without tickling or putting pressure on the infant's skin, and if the infant is uncomfortable, it will be stopped immediately. The infant should be placed in a quiet and bright environment on the bed with the head at an angle of 30 to 45 degrees to the back. After washing the hands and heating them to reduce the friction, the researcher smeared the hands with "Version" olive oil and after testing the oil on the infant's forearm (in terms of rejecting a possible allergy to olive oil), She will perform the massage in the abdominal area in the "I Love U" method. In this way, the first touch is in the form of the letter I from top to bottom on the left side of the navel, the second touch is in the form of the letter L in reverse from right to left in the lower stomach, and the third touch is in the form of the letter U in reverse from right to left in the area around the navel.
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Rezaie Ashtiani hospital

Full name of responsible person
Mahbobeh Sajadi

Street address
Next to Amir al-Mominin Hospital, Basij Sq., Sardasht region, Arak city

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golmehrsherafati@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
DR Dawood Hekmatpoo

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
Arak University of Medical Sciences

Proportion provided by this source
80

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
Arak University of Medical Sciences

Full name of responsible person
Mahbobeh Sajadi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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University complex of Arak medical sciences, Basij square, Sardasht.

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Person responsible for scientific inquiries

Contact

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Position
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Latest degree
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Only the part of the data related to the original outcome will be able to be shared.
When the data will become available and for how long
since the winter of 2025
To whom data/document is available
Researchers and students in this field
Under which criteria data/document could be used
In order to increase weight and reduce serum bilirubin levels and improve digestive outcomes in premature infants.
From where data/document is obtainable
Vice chancellor for education and research, Arak university of medical sciences
What processes are involved for a request to access data/document
These documents will be available on the website of Arak university of medical sciences.
Comments