Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of three methods of foot massage, kangaroo care and standard care on bilirubin level and physiological indicators of term neonates with physiological jaundice

Protocol summary

Study aim
Comparison of three care methods on the bilirubin level of full-term infants with physiological jaundice

Design
The clinical trial consisted of two intervention groups, one control group, parallel group trial, single -blind and randomized on 84 term neonates with physiological jaundice. infants are assigned to groups based on a randomization sequence that will be generated in advance, which is unpredictable. To assign samples to 3 groups, the block randomization method with random number generator software will be used. This will be done with software called Sealed Envelope.

Settings and conduct
This study will be performed in Shohada Hospital in Qom. After the phototherapy of each of the three groups, their bilirubin levels are measured and recorded, then SPSS version 22 software is used to interpret the data and the variables are interpreted. Only data analyzers will not know how the samples are placed in the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: no underlying, congenital and infectious diseases; term infants; birth weight over 2,500 grams; exclusive breastfeeding. Exclusion criteria: Infant parents' unwillingness to participate in the study; The presence of problems in the soles of the feet

Intervention groups
First intervention group: Babies is placed on the bed lying on his back, and researcher holds the baby's heel and massages the relevant area in a controlled manner. Second intervention group: In kangaroo care group babies with the KMC method, the mother with kangaroo care clothes is placed in a semi-sitting position, and the naked baby will be placed between the mother's breasts. Control group: In this group there is no intervention.

Main outcome variables
bilirubin level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210501051142N3**
Registration date: **2022-08-02, 1401/05/11**
Registration timing: **prospective**

Last update: **2022-08-02, 1401/05/11**
Update count: **0**

Registration date
2022-08-02, 1401/05/11

Registrant information

Name
Aida Arjloo

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 86 3402 0115

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-02, 1401/07/10

Expected recruitment end date
2023-01-30, 1401/11/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of three methods of foot massage, kangaroo care and standard care on bilirubin level and physiological indicators of term neonates with physiological jaundice

Public title
Comparison of three methods of foot massage, kangaroo care and standard care on bilirubin level and physiological indicators

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
No underlying, congenital and infectious disease Term infants (gestational age equal to or greater than 37 weeks) Birth weight over 2,500 grams Exclusive breastfeeding

Exclusion criteria:
Infant parents' unwillingness to participate in the study The presence of problems in the soles of the feet (edema, tissue damage, skin infection, skin rashes, fractures) Need for blood transfusion

Age
From **1 day** old to **21 days** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Infants are assigned to two intervention groups and one control group based on the randomization sequence that will be generated in advance, which is unpredictable and its arrangement is completely random. To allocate the samples, the block randomization method with the size of 3 blocks will be used, so that by using the software for generating random numbers in the block method, a randomization sequence will be generated according to the sample size required for the three groups. First, all the modes in which the 3 letters A, B and C can be put together in blocks of 3 are generated, then a block is randomly selected by placing it among the blocks and the layout pattern in that block will be used to allocate infants. Finally this block will be placed in the main container and another block will be selected again. Blocks of 3 will all be in the same container. 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)
Single blinded

Blinding description
The data analyzer will not know how the samples are placed in the intervention and control groups. Other people in the study will be aware of this placement.

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
2022-07-02, 1401/04/11

Ethics committee reference number
IR.ARAKMU.REC.1401.077

Health conditions studied

1

Description of health condition studied
Physiological jaundice

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Bilirubin level

Timepoint
Every 24 hours

Method of measurement
The baby'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
Intervention group1: Babies in the reflexology group receive massage in the respective specific area, in such a way that the baby is placed on the bed in a quiet and bright room lying on his back and completely relaxed, and the researcher washes his hands to prevent infection and after Warming up, first apply olive oil from Ladan Talai company made in Iran to reduce friction and then test the olive oil on the child's forearm (in order to rule out a possible allergy to olive oil) and start massaging the specific area. researcher holds the baby's heel with his left hand and massages the relevant area with his right thumb in a controlled and dedicated manner. The frequency of massage for each baby for the reflexology intervention group will be once a day for 15 minutes (30 minutes in total for both legs of the baby).

Category
Other

2

Description
Intervention group2: In the babies of the kangaroo care group by the KMC method, the mother with the kangaroo care clothes is placed on the folding bed in a semi-sitting position (40-60 degrees) or lying down and the naked baby , wearing only a diaper and a hat, will be placed between the mother's breasts with the help of a nurse. This KMC method will last for 30 minutes, so that it will be done at least five times a day (every 3 hours) in the morning, evening and night shifts during breastfeeding.

Category
Other

3

Description
Control group: Like the two intervention groups, they are treated with phototherapy. In this group there is no intervention (reflexology, KMC).

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohada hospital

Full name of responsible person
Mahbobeh Sajadi

Street address
Tohid boulevard, Northern Hekmat Ave, Qom city, Iran

City
Qom

Province
Ghoum

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3819693345

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
DR Alireza Kamali

Street address
University complex of the Great prophet, Basij square, Sardasht

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

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
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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 2023
To whom data/document is available
Researchers and students in this field
Under which criteria data/document could be used
Control of bilirubin level and physiological indicators of full-term infants with physiological jaundice
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