Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of maternal and grandmother kangaroo infant care on vital signs of premature neonates

Protocol summary

Study aim
Comparison of the effect of maternal and grandmother kangaroo infant care vital signs of premature neonates
Design
A clinical trial with a control group, with parallel groups, randomized on 80 infants. SPSS software was used for randomization.
Settings and conduct
Performing kangaroo care by mothers and grandmothers in the neonatal ward and neonatal intensive care unit of Imam KHomeini Hospital in Koohdasht city and comparing the results of the two groups
Participants/Inclusion and exclusion criteria
Premature babies between 32 and 36 weeks Premature babies weighing between 1500 and 2500 grams Premature babies who are not intubated Grandmother has a fever or an infectious disease while studying Dissatisfaction of mother and grandmother to continue working together for cuddling care Infant who need a blood transfusion while studying
Intervention groups
40 infants in the intervention group under mid-mother kangaroo care and 40 infants in the control group under kangaroo care by the grandmother
Main outcome variables
heart rate, respiration, body temperature, neonatal blood secretion

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20211225053516N1**
Registration date: **2022-01-30, 1400/11/10**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-30, 1400/11/10**
Update count: **0**
Registration date
2022-01-30, 1400/11/10

Registrant information
Name
Zahra Dargahiyan
Name of organization / entity
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Iran (Islamic Republic of)
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+98 66 3263 3861
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zdargahiyan97@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-02-19, 1399/12/01
Expected recruitment end date
2021-08-23, 1400/06/01
Actual recruitment start date
2022-01-15, 1400/10/25
Actual recruitment end date
2022-06-05, 1401/03/15
Trial completion date
2022-08-21, 1401/05/30

Scientific title
Comparison of the effect of maternal and grandmother kangaroo infant care on vital signs of premature neonates

Public title
Comparison of the effect of maternal and grandmother kangaroo infant care on vital signs of premature neonates
Purpose
Supportive
Inclusion/Exclusion criteria

Inclusion criteria:
Premature neonatal between 32 and 36 weeks Premature neonatal weighing between 1500 and 2500 gram Premature neonatal who are not intubated
Exclusion criteria:
Dissatisfaction of mother and grandmother to continue working together for cuddling care Grandmother has a fever or an infectious disease while studying The baby dose not need a blood transfusion during the study

Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Actual sample size reached: **80**
More than 1 sample in each individual
Actual sample size in each individual: **80**
Intervention group 40 and control group 40
Randomization (investigator's opinion)
Randomized
Randomization description
The samples were first selected based on purpose from among the eligible infants and then in order to standardize the distribution of sex, type of childbirth, birth weight and nutritional class confounders based on these variables as described by the boy / girl class. , Normal delivery / cesarean section, weight between 1500-2500 g was created and then randomly assigned to the control and control groups in the two groups under the care of the mother and grandmother kangaroo.
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 Lorestan University of Medical Sciences
Street address
Kamalvand Km4 of Khorramabad-Borugerd road
City
Khorramabad
Province
Lorestan
Postal code
381251698
Approval date
2020-06-06, 1399/03/17
Ethics committee reference number
IR.LUMS.REC.1399.066

Health conditions studied

1

Description of health condition studied
Effect of the kangaroo care
ICD-10 code
Z00.11
ICD-10 code description
Newborn health examination

Primary outcomes

1

Description
Vital Signs
Timepoint
Before, during, after the intervention
Method of measurement
Monitoring

2

Description
Kangaroo care
Timepoint
Before, during, after the intervention
Method of measurement
Vital Signs-Monitoring

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, kangaroo care is performed by the mother. For premature infants, vital signs including breath rate, heart rate, blood oxygen saturation and body temperature are checked 15 minutes before, 15 minutes during and 15 minutes after kangaroo care. And is compared with the Contra group.
Category
Treatment - Other

2

Description
Contorol group: In this group, kangaroo care is performed by the mother. For premature infants, vital signs including breath rate, heart rate, blood oxygen

saturation and body temperature are checked 15 minutes before, 15 minutes during and 15 minutes after kangaroo care. And is compared with the itervention group

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Bimarestan emam khomini shahrestan koohdasht bakhsh moraghebathaye vighe nozadan

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Ebrahim Fallahi

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Kamalvand 4 km Boroujerd road Khorramabad

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6814993165

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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
Khoram-Abad 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
Khoram-Abad University of Medical Sciences

Full name of responsible person
Zahra Dargahiyan

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Email

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