

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 66 3263 3861

Email address

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 intervention group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bimarestan imam khomini shahrestan koohdasht bakhsh moraghebathaye vighe nozadan

Full name of responsible person

Zahra Dargahiyan

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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

Street address

Kamalvand 4 km Boroujerd road Khorramabad

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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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Position

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Latest degree

Bachelor

Other areas of specialty/work

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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