Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Kangaroo father care and it’s effect on father & premature newborn cortisol changes

Protocol summary

Summary

The purpose of this study is evaluate the effect of father kangaroo care on the father and premature infant cortisol changes. The study is a randomized controlled clinical trial. 46 premature infants hospitalized in neonatal ward of the Tabriz Alzahra hospital with her and his father divided into two groups randomly. Inclusion criteria: preterm infants 34-37 weeks; birth weight 1200 to 2500 gr; Apgar score fifth minutes more than 7; no jaundice and one hour before performing any procedure and feed the infant; father lack of vigorous physical activity, and eating and drinking than an hour ago. Exclusion criteria: breathing and body temperature unstable situation and insufficient sample volume. In the control group, in the presence of the father done usual routine care on the infant. In Intervention group, infants by their fathers will have skin to skin contact for an hour in a room with the right temperature, Infant will be in the fetal position or flexion between the chest father.For this purpose, the father,a loose gown and the newborn will be wearing a hat and diaper and receive supportive care. At the beginning and end of the study in each of the intervention and control groups, Father venous blood samples and Infant saliva samples will be collected to measure cortisol levels in samples. Laboratory results of the samples will be compared and evaluated. In the intervention group will be monitored heart rate, respiration, oxygen saturation and temperature throughout the study time for status monitoring and maintaining the stability of infant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081513691N5**
Registration date: **2015-11-13, 1394/08/22**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-11-13, 1394/08/22

Registrant information

Name
Mohammad Arshadi Bostanabad
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 41 3479 6770
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz Medical Sciences University

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Kangaroo father care and it’s effect on father & premature newborn cortisol changes

Public title

Kangaroo father care and it’s effect on father & premature newborn cortisol changes

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria: premature infants 34-37 week; weight 1200-2500 grams; no heart failure and respiratory problems; apgar score in the fifth minute over than 7; non-sedating medicines; Non icteric; 24 hours after birth; one hour after any procedure and infant feeding; no defects in the pituitary - hypothalamic – adrenal and fathers literacy; proven lack of mental health problems; No disability of the in the implementation of care; the absence of renal and hepatic disease; Not taking medications such as: Corticosteroids, Spironolactone, Metoclopramide, Phenytoin and Morphine (from a week ago); Non-smoking and alcohol; No eating, drinking and strenuous physical activity (One hour before the sampling). Exclusion criteria: unstable respiratory condition and temperature; lack of parental consent for re-sampling; the reluctance of parents to continue the study; insufficient volume of sample.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Research Vice-Chancellor, Floor 3, No 2 Central Building, Tabriz University of Medical Sciences, University Street

City

Tabriz

Postal code

5166615953

Approval date

2015-09-02, 1394/06/11

Ethics committee reference number

TBZMED.REC.1394.489

Health conditions studied

1

Description of health condition studied

stress

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder

Primary outcomes

1

Description

cortisol

Timepoint

5 minutes before and 5 minutes after intervention

Method of measurement

ng/ml

Secondary outcomes

1

Description

neonatal heart rate

Timepoint

Every 15 minutes since the beginning of the intervention

Method of measurement

Pulse Oximeter

2

Description

neonatal breath

Timepoint

Every 15 minutes since the beginning of the intervention

Method of measurement

Observation

3

Description

neonatal Arterial blood oxygen saturation

Timepoint

Every 15 minutes since the beginning of the intervention

Method of measurement

Pulse Oximeter

4

Description
neonatal body temperature
Timepoint
Every 15 minutes since the beginning of the intervention
Method of measurement
Thermometer

Intervention groups

1

Description
In the intervention group, kangaroo care will be done after oral training and provide educational pamphlets to father. Infant is wearing only a diaper and cap will be in the fetal position or bending directly at skin to skin contact with father chest for an hour. For this purpose for the father would be considered a room in adjacent to the ward that the temperature is in the standard range and features such as bed and comfortable chair. Father embraces infant a quiet environment. Loose clothing that will be worn by a father, Infant will be protected, the creation of a fetal position or flexion for infant will be flexed to cause continuous coverage without creating pressure points or wrinkles and protect the infant from the air flow will be drawn a blanket over infant and father. In the intervention group, the distance of 5 minutes before and after the kangaroo intervention will be collected father blood sample and infant saliva sample to measure levels of cortisol. In the intervention group will be monitored heart rate, respiration, oxygen saturation and temperature throughout the study time for status monitoring and maintaining the stability of infant.
Category
Other

2

Description
In the control group, routine usual cares will be carried out in the presence of father on infant and collect father blood sample and infant saliva sample will be performed before and after the duration of the study to assess the level of cortisol. In the control group, in addition to cortisol testing, CBC will be free to maintain the ethics of sampling.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Uiversity Hospital
Full name of responsible person
Mir Hamid Razzaghi
Street address
Baghshmal Cross, South Artesh St.
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
DR Mohammad Reza Rashidi
Street address
Research vice chancellor, Tabriz University of Medical Sciences, University Street
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Arshadi Bostanabad Mohammad
Position
PhD
Other areas of specialty/work
Street address
Nursing and Midwifery Faculty, South Sharyati St
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5138947977
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+98 41 1479 6770
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Email
arshadi@tbzmed.ac.ir; arshadi_m@yahoo.com
Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty