Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effect of kangaroo care by mother and surrogate on nutritional behavior of preterm neonates : A randomised controlled clinical trial

Protocol summary

Study aim
Comparison of neonate nutritional behavior score between two groups on days 1,2,3,4,5 after intervention with baseline score control

Design
Randomized clinical trial with control group, parallel, sample size of 80

Settings and conduct
This study is a randomized controlled clinical trial. After obtaining permission from the Ethics Committee and registration at Iran Clinical Trials Center, the researcher will begin the daily sampling of 80 premature neonates in Alzahra and Taleghani Hospitals through convenience sampling. After evaluating inclusion and exclusion criteria, the goals and methods will be explained to mothers. Samples will be randomly divided and stratified based on neonate`s age (31-32,6 and 33-35 weeks old) with blocks size 4 , 6 with 1:1 ratio in two groups: intervention group, 3 times of daily care once by mother and twice by surrogate in the last two times of care and the control group 3 times of daily care by mother (up to 5 days each time 60 minutes).Allocation sequences will be determined using RAS. Allocation concealment will be done using opaque-sealed envelopes numbered in sequence and opened by someone other than the researcher. Nutritional behavior will be measured using the Preterm Infant Breastfeeding Behavior Scale and physiological outcomes; temperature will be measured with a thermometer; heart-rate and arterial oxygen saturation will be checked with Pulse-oximeter; respiratory rate will be tested by chest touch and observation once before intervention and once again afterwards for up to 5 days.

Participants/Inclusion and exclusion criteria
31-35 weeks neonates, weighing more than 1500 g and no connection to ventilator Gravida 1,2

Intervention groups
Intervention: Three times a day of care, once by mother - two times surrogate Control:Three times a day of mother's care

Main outcome variables
Nutritional behavior score of preterm infant

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150424021917N10**
Registration date: **2020-04-22, 1399/02/03**
Registration timing: **prospective**

Last update: **2021-01-21, 1399/11/02**
Update count: **1**

Registration date
2020-04-22, 1399/02/03

Registrant information

Name
Sevil Hakimi

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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hakimis@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-04, 1399/02/15

Expected recruitment end date
2020-10-06, 1399/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of kangaroo care by mother and surrogate on nutritional behavior of preterm neonates : A randomised controlled clinical trial

Public title
The effect of kangaroo care by mother and surrogate on nutritional behavior of preterm neonates : A randomised controlled clinical trial
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Gravida 1,2 31-35 weeks neonates Neonate weight more than 1500 g unfixed female surrogate
Exclusion criteria:
Neonatal sepsis Neonate connection to ventilator CPAP use Catheter in umbilical vein Prescribing any medication to the neonate that may affect it's sleep Neonate intra ventricular hemorrhage Cleft lips and cleft palate Mother's epilepsy or surrogate Mother's or surrogate's addiction to any drug New scare in part of mother's/surrogate's body that is in direct contact with baby's Skin rash Use of perfume and perfume soap
Age
From **217 days** old to **245 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples will be randomly divided and stratified based on neonate`s age (31-32,6 and 33-35 weeks old) with 4 and 6 blocks with 1:1 ratio in two groups: intervention and control groups. Allocation sequences will be determined using RAS. Allocation concealment will be done using opaque-sealed envelopes numbered in sequence and opened by someone other than the researcher.
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 Tabriz University of Medical Sciences
Street address
Research department, Third floor, Central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan
City
Tabriz
Province
East Azarbaijan
Postal code
5138665793
Approval date
2020-02-03, 1398/11/14
Ethics committee reference number
IR.TBZMED.REC.1398.1213

Health conditions studied

1

Description of health condition studied
Preterm neonates
ICD-10 code
P07.33
ICD-10 code description
Preterm newborn, gestational age 30 completed weeks

Primary outcomes

1

Description
Nutritional behavior of preterm neonate
Timepoint
Once before the intervention and once again after the intervention for up to 5 days
Method of measurement
Using the questionnaire Preterm Infant Breastfeeding Behavior Score (PIBBS)

Secondary outcomes

1

Description
Nutritional effect
Timepoint
once before the intervention and once again after the intervention for up to 5 days
Method of measurement
With using of standard questionnare

2

Description
Physiological function of preterm neonate (heart rate, temperature, respiratory rate and arterial oxygen saturation)
Timepoint
once before the intervention and once again after the intervention for up to 5 days
Method of measurement
temperature will be measured with a thermometer; heart-rate and arterial oxygen saturation will be checked with Pulse-oximeter; respiratory rate will be tested by chest touch and observation.

Intervention groups

1

Description
Intervention group: Mother/surrogate kangroo care, 3 times of daily care once by mother and twice by surrogate in the last two time of care up to 5 days each time 60 minutes
Category
Behavior

2

Description
Control group: 3 times of daily care by mother up to 5 days each time 60 minute
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Khalij e Fars Hospital, Bandar Abbas
Full name of responsible person
Sevil Hakimi
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2

Recruitment center
Name of recruitment center
Children's Educational and Medical Center, Bandar Abbas
Full name of responsible person
Sevil Hakimi
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Golshar Shomali, Emam Khomeini blvd,Bandar Abbas
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Mohammad Samiei
Street address
Research department, Third floor, Central construction, Number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz
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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
Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person
Mahboubeh Jamehdar

Position
MSc student of Midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
South Shariati Street, Nursing & Midwifery Faculty, Tabriz University of Medical Sciences

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Person responsible for scientific inquiries

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Full name of responsible person
Sevil Hakimi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

Contact

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Position
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Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not 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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Only part of the information, such as information on the main outcome or the like, can be shared. The results of clinical study will be published as article.

When the data will become available and for how long
Start publishing period 6 months after printing results. Immediately after publishing the results.

To whom data/document is available
All researchers

Under which criteria data/document could be used
Scientific using with citation to article

From where data/document is obtainable
Sevil Hakimi hakimis@tbzmed.ac.ir

What processes are involved for a request to access data/document
The applicant sends an application via e-mail. After receiving the email, the results will be sent.

Comments