

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative effect of maternal holding and massage on heel blood sampling, physiological responses, and pain in neonates

Protocol summary

Study aim

Determining the effect of maternal holding and massage on heel blood sampling, physiological responses, and pain in neonates

Design

The study included three groups that had two intervention groups and one control group. An intervention group is the mother's embrace which the baby is considered to be in the mother's arms. A massage group that deals with the massage of the baby's leg. And the control group that receives the usual interventions of the health center. The study included a sample of 135 infants aged 38 to 42 weeks. Sampling and interventions are carried out at Bandar Abbas Health Center. The samples were allocated to intervention and control groups according to the day of referral to the health center and there was no randomization in the selection of samples.

Settings and conduct

Sampling and interventions are carried out at Bandar Abbas Health Center. The samples were allocated to intervention and control groups according to the day of referral to the health center and there was no randomization in the selection of samples.

Participants/Inclusion and exclusion criteria

Healthy full-term infants (38 to 42 weeks) Birth weight 2500-4000 grams Apgar more than 7 at birth. Stability in terms of clinical condition Stable in terms of clinical condition infants at 4th to 6th birthday who to screen for hypothyroidism.

Intervention groups

Intervention group: In the mother's embrace group, the infants are placed in their mother's arms two minutes before, during and at least 15 seconds after blood sampling, with the difference that they are not breastfed. All infants will be awake when applying this procedure. Their mothers sit on the comfort seat and will be allowed to cuddle their babies when they cry during blood sampling. In the massage group before blood sampling,

the researcher gently massages the baby's foot from the fingertips to the middle of the thigh, massage with the effleurage technique will be done with the thumb of one hand for 2 minutes, and the place of massages will be covered for one minute with a warm towel. Massage is used to move the contents of the superficial lymph vessels and blood vessels to facilitate blood circulation as well as to manipulate tissue fluids. The effleurage is done through the flow direction of venous to the heart. Massage is soft, smooth, uniform and constant, and always from the point of return of the vessels (distal) to the primary areas (proximal). In the control group, the routine procedure of the health center (sleeping on the bed during blood sampling) is performed. It should be noted that all blood sampling is carried out under the same conditions with the same facilities and by one of the health center personnel.

Main outcome variables

Pain, crying time, physiological indices (heart rate, respiration, oxygen saturation)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170116031972N4**

Registration date: **2018-02-27, 1396/12/08**

Registration timing: **retrospective**

Last update: **2018-02-27, 1396/12/08**

Update count: **0**

Registration date

2018-02-27, 1396/12/08

Registrant information

Name

Mahlagha Dehghan Anari

Name of organization / entity

Kerman University of Medical Sciences

Country	Iran (Islamic Republic of)	Assignment	Not used
Phone	+98 34 3132 5201	Other design features	Parallel
Email address	m_dehghan@kmu.ac.ir	Secondary Ids	empty
Recruitment status	Recruitment complete	Ethics committees	
Funding source		1	
Expected recruitment start date	2017-05-22, 1396/03/01	Ethics committee	
Expected recruitment end date	2017-07-22, 1396/04/31	Name of ethics committee	Ethics committee of Kerman University of Medical Sciences
Actual recruitment start date	2017-05-22, 1396/03/01	Street address	Ebnesina St.Jahad Blvd, Somaye Crossroad, Kerman
Actual recruitment end date	2017-07-22, 1396/04/31	City	Kerman
Trial completion date	empty	Province	Kerman
Scientific title	Comparative effect of maternal holding and massage on heel blood sampling, physiological responses, and pain in neonates	Postal code	7815789957
Public title	Comparative effect of maternal holding and massage on heel blood sampling, physiological responses, and pain in neonates	Approval date	2017-04-04, 1396/01/15
Purpose	Supportive	Ethics committee reference number	lr.kmu.rec.1395.998
Inclusion/Exclusion criteria		Health conditions studied	
Inclusion criteria:	Healthy full-term infants (38 to 42 weeks) Birth weight 2500-4000 grams Apgar more than 7 at birth. Stability in terms of clinical condition infants at 4th to 6th birthday who to screen for hypothyroidism.	1	
Exclusion criteria:	Having any congenital and chromosomal anomalies Having painful interventions such as circumcision and getting the peripheral vein before referring to the health center	Description of health condition studied	Pain, crying time due to blood sampling, physiological symptoms (heart rate, respiration rate, and oxygen saturation)
Age	From 266 days old to 294 days old	ICD-10 code	
Gender	Both	ICD-10 code description	
Phase	N/A	Primary outcomes	
Groups that have been masked	No information	1	
Sample size	Target sample size: 135 Actual sample size reached: 135	Description	The initial outcome could be an increase or decrease in the pain score
Randomization (investigator's opinion)	Not randomized	Timepoint	The pain score measurement is done at the beginning of the study (before the intervention), immediately after blood sampling, and 5 minutes after blood sampling
Randomization description		Method of measurement	Neonatal Infant Pain Scale (NIPS)
Blinding (investigator's opinion)	Not blinded	2	
Blinding description		Description	The initial outcome could be an increase or decrease in the baby's crying time
Placebo		Timepoint	The time interval for the measurement of the crying time

is after blood sampling
Method of measurement
Stop watch

Secondary outcomes

1

Description

The initial outcome could be an increase or decrease in the heart rate

Timepoint

Heart rate measurement as a secondary outcome is done at the beginning of the study (before the intervention), immediately after blood sampling, and 5 minutes after blood sampling

Method of measurement

Pulse Oximeter

2

Description

The initial outcome could be an increase or decrease in SPO2

Timepoint

SPO2 measurement as a secondary outcome is done at the beginning of the study (before the intervention), immediately after blood sampling, and 5 minutes after blood sampling

Method of measurement

Pulse Oximeter

3

Description

The initial outcome could be an increase or decrease in respiratory rate

Timepoint

Respiratory rate measurement as a secondary outcome is done at the beginning of the study (before the intervention), immediately after blood sampling, and 5 minutes after blood sampling

Method of measurement

Pulse Oximeter

Intervention groups

1

Description

Intervention group: In the mother's embrace group, the infants are placed in their mother's arms two minutes before, during and at least 15 seconds after blood sampling, with the difference that they are not breastfed. All infants will be awake when applying this procedure. Their mothers sit on the comfort seat and will be allowed to cuddle their babies when they cry during blood sampling.

Category

Other

2

Description

Intervention group: In the massage group before blood sampling, the researcher gently massages the baby's foot from the fingertips to the middle of the thigh, massage with the effleurage technique will be done with the thumb of one hand for 2 minutes, and the place of massages will be covered for one minute with a warm towel. Massage is used to move the contents of the superficial lymph vessels and blood vessels to facilitate blood circulation as well as to manipulate tissue fluids. The effleurage is done through the flow direction of venous to the heart. Massage is soft, smooth, uniform and constant, and always from the point of return of the vessels (distal) to the primary areas (proximal).

Category

Other

3

Description

Control group: In the control group, the routine procedure of the health center (sleeping on the bed during blood sampling) is performed. It should be noted that all blood sampling is carried out under the same conditions with the same facilities and by one of the health center personnel.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tohid Health Center

Full name of responsible person

Zahra Aliyas

Street address

Tohid Town, Bandar Abbas, Hormozgan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

Street address

Kerman University of Medical Sciences, Medical
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vcr@kmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kerman 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**

Kerman University of Medical Sciences

Full name of responsible person

Atefe Roshanray

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is still no plan to develop a program for sharing the data. According to the above sampling data time, the study will be completed by that time.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available