

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Investigating the effect of maternal body massage on infant pain due to invasive procedures in premature infants, neonatal intensive care unit

Protocol summary

Study aim

Investigating the effect of maternal body massage on infant pain due to invasive procedures in premature infants, neonatal intensive care unit

Design

A clinical trial with two intervention groups, massage and control group, without massage, examines the effect of massage by the mother on her infant during the hospitalization period. The intervention group and the control group are both under routine care and conventional therapies.

Settings and conduct

After receiving the approval of the ethics committee of Iran University of Medical Sciences and permission to attend the neonatal ward of Hazrat Ali Asghar Hospital

Participants/Inclusion and exclusion criteria

Admission requirements: It is possible for the mother to be present with the baby 24 hours a day, to feed the baby. Non-addiction of mothers to drugs and alcohol. The baby is the result of a twin. Permission for complete oral feeding of the infant through the mother's breast should be issued according to the doctor's instructions. Infants should have stable clinical conditions. Infants should not undergo phototherapy. At least 3 days have passed since the infant was admitted to the neonatal care unit. Massage the entire surface of the baby's body, not like having a chest tube or ventilator.

Intervention groups

This study is a clinical trial study. 42 infants with a gestational age of 29 to 37 weeks in the neonatal intensive care unit were selected by random sampling and randomly divided into two groups. In both groups, pain is measured before, during and after the intervention with the NIPS questionnaire. be

Main outcome variables

pain

General information

Reason for update

Acronym

نوزادان نارس

IRCT registration information

IRCT registration number: **IRCT20141216020344N4**

Registration date: **2021-03-10, 1399/12/20**

Registration timing: **prospective**

Last update: **2021-03-10, 1399/12/20**

Update count: **0**

Registration date

2021-03-10, 1399/12/20

Registrant information

Name

Hamidreza Khoshnezhad Ebrahimi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7787 2189

Email address

khoshnezhad.hr@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of maternal body massage on infant pain due to invasive procedures in premature infants, neonatal intensive care unit

Public title

Investigating the effect of maternal body massage on infant pain due to invasive procedures in premature infants, neonatal intensive care unit

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

It is possible for the mother to be with the baby 24 hours a day to feed the baby. Non-addiction of mothers to drugs and alcohol The baby is the result of a twin. The weight of the baby at birth is 2500 grams and more The gestational age of infants is 29 to 37 weeks Permission for complete oral feeding of the infant through the mother's breast is issued according to the doctor's instructions. Infants have stable clinical conditions Babies should not be undergoing phototherapy. - At least 3 days have passed since the baby was admitted to the neonatal care unit The baby should not be attached to equipment that prevents massaging of the baby's entire body, such as a chest tube or ventilator

Exclusion criteria:

Discharge of the infant before the end of the intervention Disruption of stability and general conditions of mother and baby

Age

From **1 day** old to **30 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling method will initially be done randomly using the table of random numbers in the statistical reference book. The first choice from the table of even random numbers will be the sampling of the control group. Sampling in the control and test groups will be done by systematic randomization; In this way, according to the time specified in Jules Gantt for sampling, which is estimated to be 90 days (3 months), and also after reviewing and calculating the approximate number of admissions in the hospital, the number of samples that the conditions and The inclusion criteria for the present study are estimated to be one infant per day (approximately 90 eligible infants will be admitted to the hospital within 90 days). To get 21 samples in each group, divide 90 by 21 and it is approximately equal to 4. In this way, from the day of sampling, the first, fourth, eighth, twelfth and (multiple of 4) who are admitted to the hospital will be selected for sampling to achieve the required number of samples. (These numbers will be

observed in sampling of both control and test groups

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 Iran University of Medical Sciences

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2021-01-12, 1399/10/23

Ethics committee reference number

IR.IUMS.REC.1399.1121

Health conditions studied**1****Description of health condition studied**

premature infants

ICD-10 code

P07.30

ICD-10 code description

Preterm newborn, unspecified weeks of gestation

Primary outcomes**1****Description**

pain

Timepoint

Before, during and after the intervention

Method of measurement

Neonatal Infant Pain Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, a booklet with an educational CD about massage training prepared by the Department of Neonatal Health is given to mothers. (Massage from head to toe while the baby's body is uncovered or only has diapers). Massage training video for mothers is shown by the researcher. Massage training classes are held in the conference hall of the hospital. All health protocols are observed. Before rushing to class, their vital signs are checked and they are asked about the history of contact with a person with coronary artery, and gloves and masks are provided to them, and the class is performed individually. The training sessions are performed in 2 one-hour sessions. The mothers practiced the massage on the model in the presence of the researcher, through face-to-face training, if the mother needed more sessions and hours to train. It will continue until he learns to massage properly. Proper performance of massage The fact that all mothers have a correct understanding of massage training is controlled by the researcher by observing the massage performed by mothers on the replica. In all stages of film distribution to teach massage, and practical massage practice, the researcher will be present to provide more explanations and solve the problems and questions of mothers. The first massage of the baby was done by the mother, with the presence of the researcher. In the intervention group massage for 5 days by mothers conducted in the procedure (venipuncture) pain is done, during and after the procedure will be calculated according to NIPS tool.

Category

N/A

2

Description

Control group: In the neonatal control group, they do not receive any intervention other than routine care, and the pain score before, during and after the procedure will be calculated according to the NIPS instrument.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Ali Asghar Hospital in Tehran

Full name of responsible person

Dr. Hamidreza Khoshnezhad Ebrahimi

Street address

Tehran, Modares Highway, after Mirdamad Bridge, Shahid Dastgerdi St. (Zafar), Hazrat Ali Asghar Children's Hospital

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Fax

Email

Khoshnezhad.hr@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Abbas Motavlian

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Khoshnezhad Ebrahimi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatric Emergency Medicine

Street address

Tehran, Modares Highway, after Mirdamad Bridge,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Khoshnezhad Ebrahimi

Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr. Hamidreza Khoshnezhad Ebrahimi

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data is encrypted in order to make the identities of
individuals unidentifiable and confidential

When the data will become available and for how long

From the end of sampling to 6 months after the
publication of the article

To whom data/document is available

University Ethics Committee, Project Arbitration
Committee, Article Arbitration Committee and other
researchers

Under which criteria data/document could be used

Perform systematic review or meta-analysis by
mentioning the document

From where data/document is obtainable

Dr. Hamidreza Khoshnezhad Ebrahimi

What processes are involved for a request to access data/document

After submitting the application via academic email, we
will provide information files to individuals within a
maximum of one week

Comments