

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Studying the Effect of Massage Therapy on the Pain Caused by Umbilical Venous Catheter in Premature Infants.

Protocol summary

Study aim

Studying the Effect of Massage Therapy on the Pain Caused by Umbilical Venous Catheter in Premature Infants

Design

In this study, 50 Premature Infants who meet the inclusion criteria, are selected. Participants are randomly divided into Intervention Group and Control Group and a code was assigned to each participant to hide the intervention group.

Settings and conduct

After obtaining permission from the University Ethics Committee and submitting a letter of introduction from the School of Nursing and Midwifery of Mashhad Educational Center for Research and Therapy of Ghaem and getting permission from the authorities in the NICU Educational Center for Research and Therapy Ghaem, the data were collected from the NICU of Ghaem hospital. Given the fact that the researcher is employed in this ward, they decided to select this setting for the research.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Premature Infants needing to have an Umbilical Vein Catheter in the NICU. The age between 30-37 weeks. Infants weighing over 1000 grams. The PIPP score is less than 7 before insertion of the Venous Catheter. Exclusion Criteria: Apgar at minute 1 less than 5, and Apgar at minute 5 minutes less than 7. Symptoms of hypoxic-ischemic encephalopathy (HIE). The PIPP score is less than 7 before insertion of the venous catheter.

Intervention groups

After the Infants are stabilized, they are placed on a reanimator under the same conditions (Light, Temperature, Noise), then Massage with the Field Technique is performed for 15 minutes. The Massage time is 15 minutes and includes 3 five minute phases. After completion of Massage, the vital signs and the pain will be measured using PIPP. Then, the Catheter, which is

the same for all Infants will be applied under sterile conditions by a Resident who has completed six months of residency. During the insertion of the Venous Catheter, and immediately after it, and 2 and 5 minutes later, the Pain and Vital Signs will be measured using PIPP.

Main outcome variables

The Infans who have received Massage, will experience less pain during the administration of the Venous Catheter.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180116038385N1**

Registration date: **2018-03-17, 1396/12/26**

Registration timing: **prospective**

Last update: **2018-03-17, 1396/12/26**

Update count: **0**

Registration date

2018-03-17, 1396/12/26

Registrant information

Name

fatemeh bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3614 6729

Email address

ramezanze961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the Effect of Massage Therapy on the Pain Caused by Umbilical Venous Catheter in Premature Infants.

Public title

Effect of Massage on Neonates' Pain

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Premature Infants needing a Catheter Umbilical Vein at NICU. The ages of the Infants between 30-37 weeks. Infants weighing over 1000 grams The PIPP score less than 7 before insertion of the Venous Catheter.

Exclusion criteria:

Infants of Addicted Mothers Apgar at minute 1 less than 5, and Apgar at minute 5 minutes less than 7 Symptoms of hypoxic-ischemic encephalopathy (HIE). Use of a sedative for the infant in the past 48 hours

AgeFrom **1 day** old to **28 days** old**Gender**

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **50****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

The Researcher's assistant who controls the symptoms of Infants during a painful procedure, does not know to which group does the Infant belongs. A person who scores the Pain does not know to which group does the Infant belongs.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

Street address

Mashhad School of Nursing and Midwifery

City

Mashhad

Province

Razavi Khorasan

Postal code

9188764355

Approval date

2017-09-23, 1396/07/01

Ethics committee reference number

IR.MUMS.REC.1390.71

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

The subject is not a disease.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Reducing pain in preterm infants

Timepoint

Before massage, before and after insertion of the venous catheter, at least 2, 5 minutes after insertion of the catheter.

Method of measurement

Premature Infant Pain Profile

Secondary outcomes

empty

Intervention groups**1****Description**

After the Infants are stabilized, they are placed on a reanimator under the same conditions (Light, Temperature, Noise), then Massage with the Field Technique is performed for 15 minutes. The Massage time is 15 minutes and includes 3 five minute phases. After completion of Massage, the vital signs and the pain

will be measured using PIPP. Then, the Catheter, which is the same for all Infants will be applied under sterile conditions by a Resident who has completed six months of residency. During the insertion of the Venous Catheter, and immediately after it, and 2 and 5 minutes later, the Pain and Vital Signs will be measured using PIPP.

Category

Other

2**Description**

Control group: All of the treatment steps were identical for the infants in the control group except that they were not given massage.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

NICU, Educational and Research Center Ghaem Hospital in Mashhad University of Medical Sciences

Full name of responsible person

Hamidreza Behnam Vashani

Street address

Faculty of Nursing and Midwifery, Avicenna St., Avicenna Street, Mashhad, Iran.

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Email

ramezanze961@mums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Hamid Reza Behnam Andashani

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Faculty of Nursing and Midwifery, Avicenna St., Avicenna Street, Mashhad, Iran.

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Hamid Reza Behnam Vashani

Position

Lecturer, Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

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

Mashhad University of Medical Sciences

Full name of responsible person

Hamid Reza Behnam Vashani

Position

Lecturer, Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh bagheri

Position

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Latest degree

Bachelor

Other areas of specialty/work

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bagherifatemeh59@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only part of the information can be shared such as information on the main outcome or the like

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Data will only be available to researchers working in academic and academic institutions

Under which criteria data/document could be used

Allow data from researchers to be obtained

From where data/document is obtainable

Mashhad University of Medical Sciences, School of Nursing and Midwifery Research Council

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

Send an application to the Vice-Chancellor of the Nursing and Midwifery Faculty and review it at the Research Council and then agree / disapprove the applicant's request

Comments