

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Chinese massage on pain caused by gastric tube implantation in premature infants admitted to neonatal intensive care unit: a randomized clinical trial

Protocol summary

Study aim

Determining the effect of Chinese massage on the pain caused by oral-gastric tube placement in premature babies

Design

The total sample size is 62 people Randomized clinical trial by randomized block method with two intervention and control groups with parallel groups Not blinded 31 people in the intervention group and 31 people in the control group

Settings and conduct

Location: special care department for newborns, Imam Khomeini Hospital, Ahvaz. It is not blinded. Intervention: Hugo point massage between two index fingers and thumb, the exact location of which is on the back of the hand, between the first and second metacarpal bones, in the middle of the second metacarpal bone in its axial direction. Methodology: Pain will be measured in three stages before, during and after the intervention by means of the PIPP tool. The time required to observe the baby's behavior is 20 seconds and the behavioral and physiological indicators are 30 seconds.

Participants/Inclusion and exclusion criteria

Inclusion criteria : The gestational age is at least 28 weeks and at most 36 weeks and 6 days weight above 1500 grams Absence of mother's addiction Mother's consent to participate in the study Stability of physiological Exclusion criteria : Refusal of parents to sign the consent form

Intervention groups

In the intervention group, the Hugo point is massaged between the two index fingers and the thumb and on the back of the hand, between the first and second metacarpal bones, in the middle of the second metacarpal bone in its axial direction. The massage is performed in three one-minute sessions with an interval of 30 seconds, 5 minutes before and during the insertion

of the oral-gastric tube by the nurse related to the baby. Massage will not be performed in the control group.

Main outcome variables

1- Determining the pain score 2- Determining the amount of physiological and behavioral indicators

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230706058694N1**

Registration date: **2023-11-20, 1402/08/29**

Registration timing: **retrospective**

Last update: **2023-11-20, 1402/08/29**

Update count: **0**

Registration date

2023-11-20, 1402/08/29

Registrant information

Name

ayoub panahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3333 2093

Email address

panahi.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-13, 1402/04/22

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Chinese massage on pain caused by gastric tube implantation in premature infants admitted to neonatal intensive care unit: a randomized clinical trial

Public title

Investigating the effect of Chinese massage on pain in newborns

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Infants with a gestational age of at least 28 weeks absence of mother's addiction and use of drugs related to epilepsy and neurological disorders willingness and consent of the mother to participate in the study stable clinical and physiological condition of the infant no mechanical ventilation If the baby does not suffer from central nervous system damage he should have an order to fix the nasogastric tube. Failure to receive drugs that affect the physiological and behavioral state not performing any painful procedure at least one hour before the intervention Babies with a gestational age of up to 36 weeks and 6 days

Exclusion criteria:

Significant change in the stability of the hemodynamic state drop in arterial blood oxygen to less than 85% for 2 minutes - sudden death of the baby. early discharge of the baby with the personal consent of the parents

AgeFrom **7 days** old to **9 months** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **62****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, we will use the permutation block randomization method. In this two-group clinical trial, the size of the blocks will be 4, 6, and 8 (in this method, the number of people assigned to each group in the blocks is equal). The randomization tool is one of the random sequence generation software (software for random allocation) such as Stata or R. For concealment in the research, we use concealment allocation. By using opaque, sealed, numbered sequentially envelopes, in this method, each random sequence created is recorded on a card, and the cards inside the letter envelopes are They are placed in order. In order to maintain a random sequence, the outer surface of the envelopes is

numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of the registration of the participants, based on the order of entry of the eligible participants into the study, one of the envelopes will be opened and the allocation group of that participant will be revealed.

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 Jundi Shapur Ahvaz University of Medical Sciences

Street address

Ahvaz, Academic City, Vice-Chancellor of Research and Technology of Jundishapur University of Medical Sciences and Health Care Services, ground floor

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ahvaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2023-07-03, 1402/04/12

Ethics committee reference number

IR.AJUMS.REC.1402.198

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

pain

ICD-10 code

G89.11

ICD-10 code description

Acute pain due to trauma

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

pain

Timepoint

Before the intervention - during the intervention - up to 30 seconds after the intervention

Method of measurement

Using the Infant Pain Profile (PIPP)

Secondary outcomes

1

Description

Behavioral responses

Timepoint

Before the intervention - during the intervention - up to 30 seconds after the intervention

Method of measurement

PIPP tool

Intervention groups

1

Description

Intervention group: Necessary intervention in infants is performed by an experienced nursing expert who is proficient in the hugo massage method in infants and has the relevant certificate. First, put on a clean gown and wash your hands for three minutes, and then warm your hands with a warmer to get the right temperature. Then he determines the place of massage. The massage place is between the two index fingers and the thumb, and its exact location is on the back of the hand, between the first and second metacarpal bones, in the middle of the second metacarpal bone in its axial direction. The best way to find Hugo's point is that Find the point where the thumb and index finger connect to each other at the bottom of the wrist and after finding this point, place your finger next to the bone of the index finger and about half an inch away from the beginning, and then after that Lean slightly towards your thumb. Another way to identify the exact location of Hugo's point is to stick two thumbs and index fingers together, so that a mass is formed between these two fingers. The middle of this mass is exactly the Hugo point. To perform this type of massage, first place your thumb or other finger exactly on that point and apply pressure to this point. Perform the massage in three times of one minute and with an interval of 30 seconds, 5 minutes before embedding. Oral-gastric tube and during its insertion is done by the nurse related to the baby.

Category

Rehabilitation

2

Description

Control group: The method of doing the work in the control group is that no massage will be done, and 2-3 minutes before inserting the gastric tube during the work and 30 seconds after, the pain score and behavioral responses will be measured using the PIPP tool. became .

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Ahvaz

Full name of responsible person

Ayoub Panahi

Street address

Ahvaz, 24 meter street, twenty four meter street, Ahvazian street

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ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mehrnoosh Zakirkish

Street address

Ahvaz, Ostadan Quay, West Coast Boulevard, Golestan Boulevard

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mehr.zakerzadeh@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Ayoub Panahi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

Student

Latest degree

Bachelor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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