

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigation of the effect of four-handed method on the pain due to gastric tube insertion in premature infants in Neonatal Intensive Care Unit

Protocol summary

Study aim

Determining the effect of the four-handed method on the pain caused by gastric tube insertion in premature infants admitted to the neonatal intensive care unit.

Design

A clinical trial with control group, with parallel groups, single-blind, randomized, will be conducted on 80 premature babies.

Settings and conduct

The researcher will measure the pain level of premature babies during oral-gastric tube insertion using PIPP tool in two control and intervention groups. In the control group, oral-gastric tube insertion will be done by the routine method of the department, in the intervention group, the oral-gastric tube will be inserted using the four-hand method, and then the pain level will be compared in the two groups. The environment of this research is the NICU of Valiasr Hospital and Shariati Hospital.

Participants/Inclusion and exclusion criteria

Age at birth less than 37 weeks; lack of congenital abnormalities or genetic disorders; not having mechanical ventilation; not receiving drugs affecting the physiological and behavioral state such as anticonvulsants, sedatives, and narcotics at least in the last 24 hours; not having the painful procedure is at least half an hour before the intervention and there is no history of drug use by the mother.

Intervention groups

In the control group, oral-gastric tube placement will be done by the routine method, i.e. two-handed method, by one person, and the researcher will not do any intervention, and in the intervention group, oral-gastric tube placement will be done by the four-handed method.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220921056009N1**

Registration date: **2022-10-16, 1401/07/24**

Registration timing: **prospective**

Last update: **2022-10-16, 1401/07/24**

Update count: **0**

Registration date

2022-10-16, 1401/07/24

Registrant information

Name

Maryam Shirdel

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2248 5708

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marish161072@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of four-handed method on the pain due to gastric tube insertion in premature infants in Neonatal Intensive Care Unit

Public title

Investigation of the effect of four-handed method on the pain due to gastric tube insertion in premature infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All infants admitted to the NICU who are less than 37 weeks of age at birth.

Exclusion criteria:

Having a congenital abnormality or genetic disorder
Receiving drugs affecting the physiological and behavioral state in the last 24 hours
Having a painful procedure up to half an hour before the intervention
History of drug use by mother

Age

To 28 days old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Infants will be placed in two control and intervention groups in a simple random fashion by tossing a coin. One of the groups is head and the other is tail. A coin is tossed according to the sample size and people are randomly assigned to two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Considering that the participants in the research are infants, so they do not know about the study, so the study is considered a blind strain.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee of Ethics Faculty of Nursing and Midwifery

TUMS

Street address

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat East St., Toheed Square, Tehran

City

Tehran

Province

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Postal code

Ethics@sina.tums.ac.

Approval date

2022-08-17, 1401/05/26

Ethics committee reference number

IR.TUMS.FNM.REC.1401.068

Health conditions studied

1

Description of health condition studied

Premature infants

ICD-10 code

XXI

ICD-10 code description

Factors influencing health status and contact with health services

Primary outcomes

1

Description

Pain, four-hand method, premature baby, gastric tube

Timepoint

Before, during and 30 seconds after the intervention

Method of measurement

PIPP tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: oral-gastric tube insertion will be done by four-handed method and then the pain level will be compared in two groups. In four-handed care, in addition to the nurse inserting the gastric tube, another person also helps in this process, and this person actually provides supportive care for the baby and supports the baby's head and limbs with his two hands. When the baby is restless, he supports and maintains the baby's position by gently and gently touching the baby, and during the process of inserting the gastric tube, he can help the nurse inserting the gastric tube to improve its efficiency.

Category

Prevention

2

Description

Control group: In the control group, oral-gastric tube placement will be done by the routine method of the department, i.e. two-handed method, by one person, and the researcher will not do any intervention.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital and Imam Khomeini Hospital

Full name of responsible person

Batul Puraboli

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Tehran University, Faculty of Nursing and Midwifery,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mehrnaz Geranmayeh

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Maryam Shirdel

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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

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

Title and more details about the data/document

In the form of theses and articles

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Academic institutions

Under which criteria data/document could be used

Only with the permission of the supervisor and University of Tehran

From where data/document is obtainable

Supervisor

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

Refer to the instructor

Comments