Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative of the Effect of Gentle Human Touch Versus Sucrose on Orogastric Tube Insertion Pain and Distress in Preterm Infant Admitted to Neonatal Intensive Care Units: A randomized clinical trial

Protocol summary

Study aim

Comparative of the Effect of Gentle Human Touch Versus Sucrose on Orogastric Tube Insertion Pain and Distress in Preterm Infant

Design

Randomized clinical trial study with www.randomizer.org and cross sectional design with control group with 36 sample.

Settings and conduct

The setting is NICU in Tehran. After selecting the samples, demographic data will be recorded from the baby's medical record. the babies will be placed once as a control group and twice as intervention groups and how to receive interventions will be done using computer randomization. The values of heart rate and oxygen saturation will be recorded 5 minutes before the procedure from the monitor. Regarding scoring the distress , it will be calculated using the Neo comfort tool. In the first intervention group, GHT will be performed for 15 minutes. In the sucrose group, 5 minutes before the intervention, the infant's pain score is calculated. Immediately after the intervention and 2 minutes after the procedure, heart rate and oxygen saturation values will be recorded, and the baby's pain score will be calculated. Also, 30 seconds after the procedure, the baby's distress score will be calculated.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Being hospitalized in the neonatal intensive care unit Fetal age between 29-36 weeks Age after birth 3 to 28 days. Birth weight 1200-3000 grams Order to feed with an oral-gastric tube

Intervention groups

In this study, interventions are (putting in the position of gentle human touch or sucrose). In GHT, the researcher will wash and warm the hands, the baby will be laid on its side, one hand around the baby's head and wrap another hand around the baby's bottom .

Main outcome variables

If any of the methods are effective in reducing the amount of pain and distress of the baby, it can be used as a non-drug method of pain and distress control in babies .

General information

Reason for update

Completion of study and updating information

Acronym

IRCT registration information

IRCT registration number: **IRCT20230202057303N1**
Registration date: **2023-04-06, 1402/01/17**
Registration timing: **prospective**

Last update: **2023-10-11, 1402/07/19**
Update count: **1**

Registration date

2023-04-06, 1402/01/17

Registrant information

Name

Mona Alinejad naenie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4365 1180

Email address

mona_alinejad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

2023-04-22, 1402/02/02

Actual recruitment end date

2023-09-05, 1402/06/14

Trial completion date

empty

Scientific title

Comparative of the Effect of Gentle Human Touch Versus Sucrose on Orogastric Tube Insertion Pain and Distress in Preterm Infant Admitted to Neonatal Intensive Care Units: A randomized clinical trial

Public title

Comparative of the Effect of Gentle Human Touch Versus Sucrose on Orogastric Tube Insertion Pain and Distress in Preterm Infant Admitted to Neonatal Intensive Care Units: A randomized clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age between 29-36 weeks Corrected Age after birth 3 to 28 days Birth weight 3000-1200 grams Instructions for feeding with an oral-gastric tube

Exclusion criteria:

Receiving sedatives or anesthetics and muscle relaxants Receive any painkillers in prescription medications Having a skin disease Exposure to any painful procedure at least one hour before intubation Congenital anomalies Metabolic diseases Grade 2 and higher intracranial hemorrhage Cardiac abnormalities History of drug abuse by mother Convulsions

Age

From **29 days** old to **36 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the design of this randomized clinical trial study (crossover design), the selected infants will be placed once in the control condition and twice in the intervention conditions (gentle human touch intervention and sucrose intake intervention). The order of placing the nasogastric tube in the usual way and receiving interventions in each baby will be randomly determined. which will be assigned to the desired groups using computer randomization (www.randomizer.org), in such a way that the sequence of placement in the control and intervention conditions will be done randomly. Allocation information will only be available to a researcher.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee's Iran university of medical sciences

Street address

School of Nursing and Midwifery, Rashid Yasami St, Vali- e Asr St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2023-01-01, 1401/10/11

Ethics committee reference number

IR.IUMS.REC.1401.760

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

G89.11

ICD-10 code description

Acute pain due to trauma

2

Description of health condition studied

distress

ICD-10 code

F45.4

ICD-10 code description

The predominant complaint is of persistent, severe, and distressing pain, which cannot be explained fully by a physiological process or a physical disorder, and which occurs in association with emotional conflict or psychosocial problems that are sufficie

Primary outcomes

1

Description

Pain, Distress

Timepoint

3 days in a row

Method of measurement

The Premature Infant Pain Profile: Revised- Comfort neo scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: gentle human touch, oral sucrose

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasol Akram hospital

Full name of responsible person

Mona Alinejad Naiene

Street address

Hazrat Rasool Akram Hospital, corner of Mansouri St., Niayesh St., Sattar Khan St., Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

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

Mona Alinejad Naene

Position

Assisstant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

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Full name of responsible person

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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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 no further information

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

No - There is not a plan to make this available