# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Jul 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

**Contact**

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**Latest degree**

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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