Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison the effect of mother- delivered Stroking and Gentle Human Touch on Maternal Attachment behaviors, Vital Signs, and Comfort of Preterm Infants During Invasive Procedures gastric catheter insertion in the NICU

Protocol summary

Study aim
To compare the effects of maternal stroking and maternal gentle human touch on maternal attachment behaviors, neonatal vital signs, and comfort of preterm infants during nasogastric tube insertion in the Neonatal Intensive Care Unit (NICU).

Design
three study groups using a pre-generated randomization sequence create with Microsoft Excel (control, GHT, stroking). Three-arm randomized controlled clinical trial conducted among 90 mother–preterm infant dyads with a gestational age of 32 weeks to 36 weeks + 6 days, admitted to the NICU

Settings and conduct
This study will be conducted at Mahdieh Hospital, Tehran. Mother–preterm infant dyads will be randomly assigned to one of three groups: the stroking group (gentle maternal stroking of the infant's limbs at a rate of approximately 3 cm/s), the GHT group (the mother gently places her hands on the infant's head and abdomen without movement), or the control group, which will receive routine care.

Participants/Inclusion and exclusion criteria
Gestational age between 32 weeks and 36 weeks + 6 days, Hemodynamic stability, Full neonatal consciousness, as assessed by the nurse, Parents discontinuation of participation in the study

Intervention groups
The tactile intervention (stroking or Gentle Human Touch [GHT]) will begin 5 minutes before the start of the invasive procedure, continue throughout the procedure (3 minutes), and be maintained for 5 minutes after completion of the procedure. Preparation Phase include nurse notification, collection of baseline data, maternal hand washing and warming, and preparation of a calm and quiet environment.

Main outcome variables
The results of this study may contribute to the improvement of family-centered care, increase maternal active participation in managing pain and discomfort in neonates, and enhance clinical outcomes of preterm infants in the NICU.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260622069912N1**
Registration date: **2026-06-29, 1405/04/08**
Registration timing: **prospective**

Last update: **2026-06-29, 1405/04/08**
Update count: **0**

Registration date
2026-06-29, 1405/04/08

Registrant information

Name
Seyede Razie Mirsadeghi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2026-09-23, 1405/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of mother- delivered Stroking and Gentle Human Touch on Maternal Attachment behaviors, Vital Signs, and Comfort of Preterm Infants During Invasive Procedures gastric catheter insertion in the NICU

Public title

Comparison the effect of mother- delivered Stroking and Gentle Human Touch on Maternal Attachment behaviors, Vital Signs, and Comfort of Preterm Infants During Invasive Procedures gastric catheter insertion in the NICU

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age between 32 weeks and 36 weeks + 6 days Hemodynamic stability (confirmed by the attending physician) Full neonatal consciousness, as assessed by the nurse, with the ability to respond to painful stimuli No feeding within 1 hour prior to the intervention No administration of sedative or analgesic medications within 2 hours prior to the intervention No painful procedures performed within 30 minutes prior to the intervention The neonate is in a calm, awake state before the intervention begins Requirement for nasogastric (gastric) tube insertion No history of maternal substance abuse during pregnancy Written informed consent signed by the mother

Exclusion criteria:

Neurological injury Brain injury secondary to asphyxia or hypoglycemia Inborn metabolic disorders Severe respiratory distress syndrome requiring endotracheal intubation Intraventricular hemorrhage (IVH) greater than Grade II Neonatal skin disease Deterioration of the neonate's clinical condition during the study Maternal skin lesions or inability to learn the intervention Parents' withdrawal of consent or decision to discontinue participation in the study

Age

From **224 days** old to **258 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed using **Microsoft Excel** and its random number generation function.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research of the Faculties of Pharmacy, Nursing and Midwifery, Shahid Beheshti Un

Street address

Tehran - Wali Asr Street - Niaish Intersection - Faculty of Nursing and Midwifery

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Province

Tehran

Postal code

1985717443

Approval date

2026-06-15, 1405/03/25

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1405.096

Health conditions studied

1

Description of health condition studied

Preterm Infants

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Infant heart rate

Timepoint

15 minutes before, immediately before, during, and 5 minutes after the procedure

Method of measurement

Infant heart monitor

2

Description

Blood oxygen saturation

Timepoint

15 minutes before, immediately before, during, and 5 minutes after the procedure

Method of measurement

Pulse oximeter percentage

3

Description

Infant's blood pressure

Timepoint

15 minutes before, immediately before, during, and 5 minutes after the procedure

Method of measurement

Blood pressure monitor

4

Description

Infant's comfort

Timepoint

15 minutes before the procedure and 5 minutes after the procedure

Method of measurement

COMFORT checklist

5

Description

Mother's attachment

Timepoint

One hour to half an hour before the procedure and the next day

Method of measurement

Avant Checklist

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Routine care

Category

Other

2

Description

Intervention group: First, stroking (gentle stroking of the infant's body by the mother at a speed of 3 cm/s)

Category

Other

3

Description

Intervention group: Second, gentle human touch (putting the mother's hands gently on the baby's head and belly without moving)

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdiyeh Hospital

Full name of responsible person

Shahrzad Zadeh Modares

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Tehran - Shush Square - Fadaian Islam St. - Shihgarkhaneh St. - Rajab Niya St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sepideh Hajian

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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

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Position
Master of Science (M.Sc.) Student in Neonatal Intensive Care Nursing
Latest degree
Bachelor
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Research protocol and research results
When the data will become available and for how long
Access period starts 6 months after publication
To whom data/document is available
Researchers and those working in the industry
Under which criteria data/document could be used
Request to the author's email
From where data/document is obtainable

razie.mirsadeghi@gmail.com

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

Send email and receive information at least 30 days after sending email

Comments