

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

Country

Iran (Islamic Republic of)

Phone

+98 21 2263 2303

Email address

razie.mirsadeghi@sbmu.ac.ir

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

City

Tehran

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
Mahdijeh Hospital
Full name of responsible person
Shahrzad Zadeh Modares
Street address
Tehran - Shush Square - Fadaian Islam St. - Shihgarkhaneh St. - Rajab Niya St
City
Tehran
Province
Tehran
Postal code
1185817311
Phone
+98 21 5506 2628
Email
mahdijeh_hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sepideh Hajian
Street address
School of Nursing and Midwifery, Opposite Shahid Rajaei Heart Hospital, Valiasr St., Intersection of Ayatollah Hashemi Rafsanjani Expressway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1996835119
Phone
+98 21 8865 5366
Email
sbnmf@sbmu.ac.ir
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

Seyede Razie Mirsadeghi

PositionMaster of Science (M.Sc.) Student in Neonatal
Intensive Care Nursing**Latest degree**

Bachelor

Other areas of specialty/work

Others

Street addressSchool of Nursing and Midwifery, Opposite Shahid
Rajaei Heart Hospital, Valiasr St., Intersection of
Ayatollah Hashemi Rafsanjani Expressway, Tehran,
Iran**City**

Tehran

Province

Tehran

Postal code

1996835119

Phone

+98 21 8865 5366

Email

razie.mirsadeghi@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyede Razie Mirsadeghi

Position

Master of Science in Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street addressNo. 20, Jahandad Alley, East Akhlaghi St., Kolahdooz
St., Shariati St**City**

Tehran

Province

Tehran

Postal code

1939843938

Phone

+98 21 2263 2303

Fax**Email**

razie.mirsadeghi@sbmu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyede Razie Mirsadeghi

Position

Master of Science in Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street addressNo. 20, Jahandad Alley, East Akhlaghi St., Kolahdooz
St., Shariati St**City**

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Province

Tehran

Postal code

1939843938

Phone

+98 21 2263 2303

Fax**Email**

razie.mirsadeghi@sbmu.ac.ir

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 FormUndecided - 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