

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Gentle Human Touch during endotracheal suctioning on procedural pain response in preterm infant admitted to neonatal intensive care units.

Protocol summary

Study aim

Determining the effect of Gentle Human Touch during suction on the pain of preterm infants admitted to the neonatal intensive care unit

Design

Clinical trial study with a crossover design, in which subjects randomly receive a sequence of either suctioning with intervention- suctioning without intervention or suctioning without intervention- suctioning with intervention. The total number of neonates is 40.

Settings and conduct

This is an experimental clinical trial. The study will be conducted in a Neonatal Intensive Care Unit, located in a teaching Akbarabadi hospital, affiliated to Iran University of Medical Sciences. In the intervention group, the neonates suctioning with Gentle Human Touch. In the control group, suction is performed only routinely.

Participants/Inclusion and exclusion criteria

Infants 27-34 weeks gestation, and weighing above 1200 grams with tracheal intubation, and require suction

Intervention groups

In the intervention group, the neonates suctioning with Gentle Human Touch. In the control group, suction is performed only routinely.

Main outcome variables

Neonatal pain in response to suction with Gentle Human Touch

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180508039587N1**

Registration date: **2018-07-03, 1397/04/12**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-03, 1397/04/12**

Update count: **0**

Registration date

2018-07-03, 1397/04/12

Registrant information

Name

Soroor Parvizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4365 1000

Email address

parvizi.s@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Gentle Human Touch during endotracheal suctioning on procedural pain response in preterm infant admitted to neonatal intensive care units.

Public title

The effect of Gentle Human Touch during endotracheal suctioning on procedural pain response in preterm infant

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Hospitalization in the neonatal intensive care unit The gestational age between 27-34 weeks The birth weight is 1200 grams and higher Having a tube in the trachea The need for mechanical ventilation Not getting sedation or anesthetic four hours before the intervention Not having skin disease and any skin contact disorder Not to be exposed to any painful activity at least one hour before the intervention The absence of congenital anomalies

Exclusion criteria:
Changing the clinical condition of the baby, such as sudden death of the baby or need for cardiopulmonary resuscitation A sudden need for sedation or anesthetic intracranial hemorrhage higher than degree II, Need to install a chest tube Having seizures

Age
From **1 day** old to **28 days** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The baby's face is captured for pain scoring during the intervention, and without naming the baby by the codes given to the infants, they are scored by the unaware assessor. The analyst is also unaware of the work routine.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran university, Yasemi Rashid Ave., Valie Asr

Ave.Tehran Town

City
Tehran

Province
Tehran

Postal code
۱۹۹۶۷۱۳۸۸۳

Approval date
2017-12-08, 1396/09/17

Ethics committee reference number
IR.IUMS.REC 1396.9411451007

Health conditions studied

1

Description of health condition studied

The effect of Gentle Human Touch during endotracheal suctioning on procedural pain response in preterm infant

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score in Premature Infant Pain Profile

Timepoint

Measurement of pain 30 seconds before suctioning without intervention and with intervention. Measuring pain in 30 seconds after suctioning with intervention and without intervention. Comparison of pain score at these times occurs.

Method of measurement

Premature Infant Pain Profile

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: To evaluate the effect of Gentle Human Touch during endotracheal suctioning on procedural pain response in preterm infant, A total of 40 neonates with entry criteria and written consent from their parents are included in the study, which is used as a cross-over design. The intervention is performed by the researcher in a Gentle Human Touch in the infants during suctioning. Will be filmed up to 30 seconds after the intervention, and the heart rate changes and arterial oxygen saturation will be recorded from the monitor. Premature Infant Pain Profile (PIPP) is used to measure neonatal pain and the pain score is recorded. The pain score is compared with the score of the recorded pain from non-interventional items.

Category

Other

2

Description

Control group: Each neonate is considered as its control. In this study, crossover design is used. Intervention and non intervention for each newborn are determined randomly.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Abadi Hospital

Full name of responsible person

Dr.Kashaki Mandana

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Molavi Street,Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Malakoti Seyed Kazem

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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

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

Parvizi Soroor

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Yes - There is 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

After Data coding in order to keep confidentiality of the participants in the research.

When the data will become available and for how long

The end of sampling till six month after article publishing.

To whom data/document is available

Ethical, reviewer and editorial committees, researchers.

Under which criteria data/document could be used

Systematic review and meta analysis or secondary analysis citation .

From where data/document is obtainable

Soroor Parvizi, parvizi.s@iums.ac.ir

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

After sending request by academic email, we will send them data files up to one week.

Comments