

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of four- handed endotracheal suctioning on physiological and behavioral responses of premature neonate hospitalized in Neonatal Intensive Care Unit

Protocol summary

Study aim

Comparison the neonatal physiological responses in study groups; comparison the neonatal behavioral responses in study groups; comparison the behavioral responses in study groups.

Design

The present study is a clinical trial. The study population consisted of all preterm infants admitted to Shariati Hospital. The number of samples was 40

Settings and conduct

During the study, the baby will be subjected to suction with a routine (dual) method by the responsible nurse and the cameraman will begin. The newborn behaviors will be observed using the ALPS-Neo checklist as well as physiological responses monitored by the researcher. In the intervention group, they begin care of the quadruple, and the researcher's support will provide care. And the neonatal behavior status is observed using the ALPS-Neo tool .

Participants/Inclusion and exclusion criteria

Infants aged 29 to 37 weeks of gestation and ectopic age less than one week; birth weight of 1000 grams or more; having a tracheal tube; mechanical ventilation. Exit criteria: having chest tube; grade 2 or more intracranial hemorrhage; receiving opiate and logo sections 4 hours before suction.

Intervention groups

During the study, the baby will be subjected to suction in a routine (dual) method by the responsible nurse and the cameraman will begin and the newborn behaviors will be observed using the ALPS-Neo checklist as well as physiological responses will be monitored and recorded. In the intervention group, they begin care of the four. And the neonatal behavior status is observed and recorded using the ALPS-Neo tool. The physiological condition will also be observed and recorded. Then the filming of the baby begins 2 minutes before the

intervention by the researcher.

Main outcome variables

Improvement of physiological and behavioral responses of infants

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180121038461N1**

Registration date: **2018-06-03, 1397/03/13**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-03, 1397/03/13**

Update count: **0**

Registration date

2018-06-03, 1397/03/13

Registrant information

Name

Somayeh Sadeghi niaraki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6609 0524

Email address

tt_8958@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of four- handed endotracheal suctioning on physiological and behavioral responses of premature neonate hospitalized in Neonatal Intensive Care Unit

Public title
The effect of four-handed endotracheal suctioning on physiological and behavioral respons of premature neonate hospitalized in Neonatal Intensive Care Unit

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Infants aged 29 to 37 weeks of gestation and uterine age less than one week Birth weight 1000 grams or more, Having an endotracheal tube The need for mechanical ventilation, The absence of congenital anomalies
Exclusion criteria:
 Having a chest tube Intracranial hemorrhage grade 2 or higher, Receive opiate and logo parts 4 hours before suction, Having any damages to the baby's head or organs such as hematoma pottery and capillary succinate

Age
From **1 day** old to **7 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The specimens were randomly selected using a two-handed suction method, followed by suction with a four-handed or first-suction method, quadriceps, and then suction, in a dual fashion, so that each baby is controlled as He will be considered

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

Ethics Committee of Tehran University of Medical Sciences

Street address

tohid sq

City

tehran

Province

Tehran

Postal code

1419733171

Approval date

2018-04-12, 1397/01/23

Ethics committee reference number

IR.TUMS.FNM.REC.1397.4949

Health conditions studied

1

Description of health condition studied

suction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Neonatal suction in infants in intensive care unit

Timepoint

Before intervention, in a double-blind manner. And once after the intervention, the quadruple method

Method of measurement

questionnaire

Secondary outcomes

1

Description

Evaluation of behavioral responses and physiological criteria of neonates

Timepoint

Once before the intervention. During the intervention and after the intervention

Method of measurement

APLS-NEO

Intervention groups

1

Description

Intervention group: first, the researcher's help with a

washed and warmed hands and with the help of the nurses responsible for the newborn begins care of the four, and the researcher's help provides support. (If the baby is restrained by a gentle touch, it will make a better position with his hands or help the baby to be calm, and in addition to the needs of the nursing carer during the suction, and if necessary, help him throughout the process And staying with the baby). From 2 minutes before doing any action, the observation begins for 30 seconds and the results are recorded. With the onset of support, the baby will be re-examined for 30 seconds. During suction and after suction, observation is performed as well as control time 5 times every 2 minutes for 30 seconds, and the neonatal behavior status is observed and recorded using the ALPS-Neo tool. The physiological status will be observed and recorded.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Somayeh Sadeghi Niaraki

Street address

Shariati Hospital, North Kargar St.

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Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Maryam Modarres

Street address

School of Nursing and Midwifery, Tohid sq.

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modarres@sina.tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Somayeh Sadeghi Niaraki

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Batool Pouraboli

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available