

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the effect of massage and prone positioning on changes of HR & SaO2 among hospitalized preterm neonates in NICUs .

Protocol summary

Study aim

1- To compare the effect of massage and prone position on HR & SaO2 changes in preterm infants.

Design

The subjects were selected through convenient sampling and the sample size was calculated by sample size formula as 21 subjects in 3 group. With regard to possible subjects' drop , 25 subjects were assigned to each group. Group 1 is position, 2 is massage and 3 is control. Then, the neonates meeting the inclusion criteria were assigned to each group (total of three groups) through random computation. In position group, infants will lay in pron position for 1 hour and then will monitor. In massage group, they will massaged based on Field massage protocol and then will monitor for 1 hour. In control group, infants will monitor without any intervention for 1 hour. The HR and SpO2 will record every 15 min.

Settings and conduct

This is an interventional cross- sectional double blind study conducted on all neonates who are hospitalized in NICUs of selected hospitals affiliated to Alborz University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Complete infant's vigilance; upper 34 wk; >1500- gr; ability of breastfeeding; RDS diagnosis; O2 dependency; need for hospitalization more than 1 week; SaO2 > 89%. Exclusion criteria: touch contraindication; derm complications; Paralysis of the limb; major congenital anomalies; asphyxia and addiction of mother; CHD; active bleeding & depended respiratory distress.

Intervention groups

Position group: Subject will be lay on prone position for 1 hour and during this time, the HR and SaO2 variation, will record every 15 min. Massage group: After receiving massage according Tiffany Field technique, the HR and SaO2 variation, will record every 15 min, during 1 hour monitoring. Control group: Subject will monitoring for 1

hour without any intervention and during this time, the HR and SaO2 variation, will record every 15 min.

Main outcome variables

Changes of HR and SaO2 in hospitalized neonates in NICU

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130202012346N2**

Registration date: **2018-01-05, 1396/10/15**

Registration timing: **retrospective**

Last update: **2018-01-05, 1396/10/15**

Update count: **0**

Registration date

2018-01-05, 1396/10/15

Registrant information

Name

Azamolmolouk Elsagh

Name of organization / entity

Isfahan University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

Alborz University of Medical Science

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-09-23, 1396/07/01
Actual recruitment start date
2017-07-23, 1396/05/01
Actual recruitment end date
2017-10-12, 1396/07/20
Trial completion date
empty

Scientific title
Comparison of the effect of massage and prone positioning on changes of HR & SaO2 among hospitalized preterm neonates in NICUs .

Public title
comparison of the effect of massage and prone positioning on VS variation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Complete infant's vigilance > 2500gr 34 - 37 wk ability of breastfeeding Hospitalization more than 1 week RDS diagnosis O2 dependency The lower limit of SaO2 = 89% Haven't any touch contraindication
Exclusion criteria:
<1500 gr major congenital anomalies asphyxia limb Paralysis >37 wk addiction of mother CHD and dependent disease active bleeding derm complications limb Paralysis

Age
From **1 day** old to **1 month** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **75**
Actual sample size reached: **75**
More than 1 sample in each individual
Actual sample size in each individual: **1**
every intervention is individualized for a neonate

Randomization (investigator's opinion)
Randomized

Randomization description
The subjects were selected through convenient sampling by drawing without replacement. With regard to 75 possible subjects' drop , 25 subjects were assigned to each group. It was listed the number and name of the group, on each drop(Position group:1, Massage group:2, control group:3). For each infant, a sheet is drawn randomly.

Blinding (investigator's opinion)
Double blinded

Blinding description
All stages of intervention will record by a Panasonic handy cam. Then, recorded films would observed and

scored by a person who will blind to assignment of neonates to three different groups. To prevent bias and prejudice, this person will unaware of the group, which the neonate she will watching belonged to, so that scoring was made based on codes

Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of medical Science

Street address

Faculty of nursing & midwifery. First Golestan- North Esteraki- Baghestan Blvd

City

Karaj

Province

Alborz

Postal code

3146883811

Approval date

2017-06-22, 1396/04/01

Ethics committee reference number

Abzums.Rec.1396.47

Health conditions studied

1

Description of health condition studied

prone position

ICD-10 code

ICD-10 code description

2

Description of health condition studied

massage

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

HR

Timepoint

1min- 15th min- 30th min- 45th min- 60th min

Method of measurement

Pulse Oximetry

2

Description

SaO2

Timepoint

1min-15th min- 30th min- 45th min- 60th min

Method of measurement

pulse Oximetry

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group : Position group: Subjects will be laid on prone position for 1 hour, then during this time, the HR and SaO2 variation, will be recorded every 15 min. This intervention will be done for 5 consecutive days in a specific hour for every infant.

Category

Other

2

Description

Intervention group 2nd: Massage group: After receiving massage according to Tiffany Field technique, the HR and SaO2 variation, will be recorded every 15 min, during 1 hour monitoring. This intervention will be done for 5 consecutive days in a specific hour for every infant.

Category

Other

3

Description

Control group: Subject will be monitored for 5 consecutive days in a specific hour, during 1 hour without any intervention and the HR and SaO2 variation, will be recorded every 15 min.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Ali Hospital

Full name of responsible person

Haleh Hatam Gooya

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

Yes

Title of funding source

Alborz university of Medical science

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
Alborz University of Medical Science
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Position
M.S.N Faculty of Nursing and Midwifery
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

Demographic information of cases include of: age, sex & weight of neonates will report in tables.

When the data will become available and for how long

6 month after publish of results.

To whom data/document is available

Staff nurses and Master of sciences that are involve with neonates.

Under which criteria data/document could be used

E-Mail request. Following the approval of the university law will apply.

From where data/document is obtainable

Deputy of Research of University

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

Requesting to Deputy of Research of University and doing administrative process

Comments