

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

comparison of two position(prone-supine) on vital parameters of premature infants with respiratory distress admitted in NICU

Protocol summary

Study aim

: Determination and comparison of two positions (prone-supine) on the vital parameters of premature infants with respiratory distress admitted to the neonatal intensive care unit of selected hospital of Baqiyatallah University of Medical Sciences, Tehran-

Design

The present study is a clinical trial t. Najmieh Hospital neonates are performed on 80 premature infants. Sampling in this study will be done in consultation with the respected professor of statistics according to Cochran's formula.

Settings and conduct

Sampling will be done randomly by first completing the initial infant evaluation : the case and control groups. The control group changes position every 3 hours, which is routine, and the case group changes position every 2 hours, . This study is performed on 80 premature infants in the neonatal intensive care unit of Najmieh Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Infants who are premature (28-35 weeks) 2. Infants who are in the first 1-3 days of their birth. 3. Infants with respiratory distress. 4. Infants who are not treated with mechanical ventilation. 5- Infants who have 75-90% oxygen saturation. 6- Infants who have more than 60 breaths per minute. 7. Infants with a heart rate of more than 160 beats per minute. 8. Infants who do not have a congenital anomaly. Exclusion criteria: 1- Death or discharge of the infant before the completion of the research period 2- Transferring the baby to another hospital

Intervention groups

The control group changes position every 3 hours, which is according to the routine section, and the case group changes position every 2 hours

Main outcome variables

The position of the lower back may affect the vital parameters of premature infants with respiratory distress
The supine position may affect the vital parameters of

infants with respiratory distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190611043863N1**

Registration date: **2021-01-02, 1399/10/13**

Registration timing: **retrospective**

Last update: **2021-01-02, 1399/10/13**

Update count: **0**

Registration date

2021-01-02, 1399/10/13

Registrant information

Name

Zahra Bashi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6647 3810

Email address

zahrabashi8@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

2019-09-23, 1398/07/01

Actual recruitment end date

2020-02-20, 1398/12/01

Trial completion date

Scientific title

comparison of two position(prone-supine) on vital parameters of premature infants with respiratory distress admitted in NICU

Public title

comparison of two position(prone-supine) on vital parameters of premature infants with respiratory distress

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1- Infants who are premature (28-35 weeks old) 2- Infants who are in the first 1-3 days of their birth 3. Infants who have respiratory distress 4. Infants who are not treated with mechanical ventilation Oxygen saturation is 90-75%. 6. Infants with respiratory rate greater than 60 in. Precise infants with heart rate exceeding 160 minutes

Exclusion criteria:

1-death or discharge of the infant before the completion of the research period 2-transfer of the infant to another hospital

Age

From **1 day** old to **3 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

To select the samples in this study, simple random sampling has been used so that the researcher by attending the neonatal ward in the morning, evening and night shifts to sample the neonates with inclusion criteria and the names of the neonates in the sheets It is written in small and separate and placed in dark nylon and using the lottery method, the sheets are taken out and placed in the case and control groups, respectively, ie the first person in the case group and the second person in the control group until the end.

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 of Tahrán Azad University of Medical Sciences

Street address

No 20,ghayomi,steert jami,steert vali aser

City

Tahrán

Province

Tehrán

Postal code

1137634461

Approval date

2020-12-15, 1399/09/25

Ethics committee reference number

38087

Health conditions studied**1****Description of health condition studied**

respiratory distress

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Critical parameters

Timepoint

1-3days of life

Method of measurement

1-vital signs sheet 2-Monitoring 3-Baby initial assessment sheet

Secondary outcomes**1****Description**

The effect of the position prone and supine on respiratory distress

Timepoint

1-3 day of life

Method of measurement

1-vital signs sheet 2-Maniying 3-baby initial assessment sheet

Intervention groups**1****Description**

Intervention group:Control group

Category

Other

Country of origin**Type of organization providing the funding**

Academic

Recruitment centers1**Recruitment center****Name of recruitment center**

Najmieh Hospital

Full name of responsible person

Zahra Bashi

Street address

No 20,ghayomi ,jami Ave,Vali aser Ave,

City

Tahran

Province

Tehran

Postal code

1137634461

Phone

+98 21 6641 3810

Email

zahrabashi8@gmail.com

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Vice President for Research and Technology

Street address

No20, ghayomi,jami Ave vali aser

City

tahrn

Province

Tehran

Postal code

1137634461

Phone

+98 21 6641 3810

Email

zahrabashi8@gmil.com

Grant name

No

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

1

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Bashi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No20, ghayomi,jami Ave vali

City

Tahran

Province

Tehran

Postal code

1137634461

Phone

+98 21 6641 3810

Email

zahrabashi8@gmail.com

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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Bashi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No20, ghayomi,jami Ave vali aser

City

Tahran

Province

Tehran

Postal code

1137634461

Phone

+98 21 6641 3810

Email

zahrabashi8@gmail.com

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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Bashi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No20, ghayomi,jami Ave vali

City

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Province

Tehran

Postal code

1137634461

Phone

+98 21 6641 3810

Email

zahrabashi8@gmail.com

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