

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of the relationship between isolation from NCPAP at 3 and 5 cm H₂O pressures with the incidence of BPD in neonates admitted to the NICU ward with a gestational age less than or equal to 32 weeks and birth weight less than or equal to 1500 grams.

Protocol summary

Study aim

Investigating the relationship between the isolation of NCPAP at 3 and 5 cm H₂O pressure with the incidence of BPD in infants admitted to the NICU department with less than 32 weeks and less or equal birth weight of 1500 grams.

Design

This study is a one-blind clinical trial with parallel groups and randomized sampling using dual randomized blocks on 206 patients.

Settings and conduct

All premature infants with gestational age less than or equal to 32 weeks and birth weight less than or equal to 1500 grams in Shahid Beheshti and Al-Zahra hospitals after receiving the code of ethics if they have inclusion criteria and after obtaining written consent from Parenting and confirmation by the neonatal specialist are included in the study and connected to the NCPAP device, and in case of stable clinical condition, the process of isolation from NCPAP begins.

Participants/Inclusion and exclusion criteria

-Inclusion criteria All premature infants with gestational age less or equal than 32 weeks and less or equal birth weight of 1500 grams and Apgar score more than 4 in 5 minutes of birth, which received NCPAP recipient for at least 24 hours immediately after birth with RDS. - Exclusion criteria: CHD, IVH, Need surgery, Major anomalies, Need to be sent to other medical centers, Receive NCPAP in less than 24 hours, Apgar score less than 4 in 5 minutes of birth, Asphyxia, Craniofacial abnormalities.

Intervention groups

The study groups based on the method of isolation from NCPAP include the isolation group from NCPAP by Sudden Stopping method (SS group) and the isolation group by Gradual Pressure method (GP group).

Main outcome variables

Reducing the incidence of BPD and its complications in premature infants and reducing the costs imposed on the health system and infants' families.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120614010026N11**

Registration date: **2022-03-13, 1400/12/22**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-13, 1400/12/22**

Update count: **0**

Registration date

2022-03-13, 1400/12/22

Registrant information

Name

Amir mohammad Armanian

Name of organization / entity

Isfahan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-07-22, 1401/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the relationship between isolation from NCPAP at 3 and 5 cm H₂O pressures with the incidence of BPD in neonates admitted to the NICU ward with a gestational age less than or equal to 32 weeks and birth weight less than or equal to 1500 grams.

Public title

Evaluation of the relationship between NCPAP use and chronic lung disease in preterm infants.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All preterm infants less than or equal to 32 weeks of gestation and weighing less than or equal to 1500 g receiving NCPAP for at least 24 hours immediately after birth with a diagnosis of RDS.

Exclusion criteria:

Congenital heart disease, Third and fourth degree intraventricular hemorrhage, Need surgery Major anomalies Need to be sent to other medical centers Receive NCPAP in less than 24 hours Apgar score less than 4 in 5 minutes of birth Asphyxia, Having Craniofacial abnormalities

AgeFrom **1 day** old to **28 days** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget sample size: **206****Randomization (investigator's opinion)**

Randomized

Randomization description

Sampling is done by Randomized by assignment method using double-blind randomized blocks, as one of the groups called A and the other B is named. The order of group A or B is an AB or BA method, and a block is formed for both eligible infants that are admitted to the NICU section. Then, based on the mother's family name and random numbers in numbers, 0 4 arrangements AB and numbers 5 9 BA arranged to reach the sample size.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, parents of neonates (participants) are blind to their baby than the type of respiratory intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Medical Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib St., Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2022-01-06, 1400/10/16

Ethics committee reference number

IR.MUI.MED.REC.1400.731

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

Bronchopulmonary dysplasia

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

Rate of Bronchopulmonary Dysplasia

Timepoint

28th birthday

Method of measurement

daily recorded sheet

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

Frequency distribution of pneumothorax

Timepoint

At the time of discharge from the hospital

Method of measurement

Using a questionnaire and daily recorded sheet

2

Description

Frequency distribution of intraventricular hemorrhage (IVH)

Timepoint

At the time of discharge from the hospital

Method of measurement

Using brain ultrasound

3

Description

Frequency distribution of Patent ductus arteriosus (PDA)

Timepoint

At the time of discharge from the hospital

Method of measurement

Using echocardiography

4

Description

Duration of oxygen dependence

Timepoint

At the time of discharge from the hospital

Method of measurement

Using a questionnaire and daily recorded sheet

5

Description

Time to reach full enteral nutrition

Timepoint

At the time of discharge from the hospital

Method of measurement

Using a questionnaire and daily recorded sheet

6

Description

Duration of hospitalization

Timepoint

At the time of discharge from the hospital

Method of measurement

Using a questionnaire and daily recorded sheet

Intervention groups

1

Description

In infants in the intervention group who are under CPAP (Continuous Positive Airway Pressure) if the clinical condition is stable at 5CmH₂O, the CPAP pressure is reduced by one every 12 hours to 3CmH₂O and then the infant is removed from the device and if necessary, Receive oxygen supplementation with hood with flow of 10 Lit / min. If SPO₂ is tolerated and maintained between 91-95% in room air for at least four hours, no oxygen supplementation is required.

Category

Treatment - Devices

2

Description

Infants in the control group under CPAP (Continuous Positive Airway Pressure) are isolated from the device if they have stable clinical conditions at 5CmH₂O pressure and, if necessary, receive supplemental oxygen by oxyhood method with a flow rate of 10 Lit / min. If SPO₂ is tolerated and maintained between 95-91% in room air for at least 4 hours, no oxygen supplementation is required.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

NICU of Shahid Beheshti hospital

Full name of responsible person

Dr. Amir Mohammad Armanian

Street address

Shahid Motahari St., Felezi Bridge, Shahid Beheshti Hospital

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2

Recruitment center

Name of recruitment center

NICU of Al-Zahra Hospital

Full name of responsible person

Dr. Amir Mohammad Armanian

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Shahid Keshvari Highway, Soffe Boulevard, Al-Zahra Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mojgan mortazavi

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Isfahan University of Medical Science, Hezar Jerib St.
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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Amir Mohammad Armanian

Position

Associate professor of Neonatology

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

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Position

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Latest degree

Subspecialist

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