

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The comparison of the effect of NIPPV and nCPAP on Brain Tissue Regional Oximetry in Preterm Neonates Weighing less than 1500 gr with RDS

Protocol summary

Summary

This article aims to find whether or not changing pressure levels without coordination with respiratory cycles affect brain perfusion in preterm neonates' brain. Newborns weighing less than 1500 gr, hospitalized at Isfahan Beheshti Hospital, who realized the inclusion criteria (Continuous Positive Pressure equal to 4 cm H₂O and Fractional Inhaled Oxygen equal to 30%) at 72 hours from birth entered the study. The exclusion criteria included the occurrence of prenatal asphyxia, air leak, PDA, and GM-IVH with grades III or IV. This study is done as a crossover randomized clinical trial on 32 newborns. The sampling started in Isfahan Beheshti Hospital from June, 2015, and continued to May, 2016. In this study, the newborns are switched from the non-invasive respiratory management system with one stable pressure level (Control group) to the non-invasive respiratory management system with varied pressure levels (Intervention group) every two hours. In order to conduct the study, using Near Infra-Red Spectroscopy, the newborns' frontal oxygen saturation is monitored every two hours in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015123110430N7**

Registration date: **2016-05-10, 1395/02/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-10, 1395/02/21

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-05-04, 1395/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of NIPPV and nCPAP on Brain Tissue Regional Oximetry in Preterm Neonates Weighing less than 1500 gr with RDS

Public title

The comparison of the effect of NIPPV and nCPAP on Brain Tissue Oxygen content in Preterm Neonates Weighing less than 1500 gr with Respiratory Distress Syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: preterm infants weighing less than

1500 gr who had been put under nCPAP respiratory support within 72 hours from birth due to RDS, and also received their first surfactant administration during the first two hours; RDS symptoms such as tachypnea, intercostal retraction, nasal flaring, grunting, and radiography suggestive of RDS; Survanta administration to achieve $FiO_2 \geq 30\%$ and $CDP \geq 5$ cm H₂O in order to maintain SpO₂ in the range of 89-95% in the right hand; IF at 72 hours from birth, newborns were under nCPAP respiratory support, and if in order to maintain SpO₂ in the range of 89-95% in the right hand, CDP was in the range of 4 to 6 cm H₂O, with FiO_2 at 30% to 40%. EXCLUSION CRITERIA: Prenatal Asphyxia (5 min Apgar between 0 to 3, umbilical cord pH less than 7, and umbilical cord Bicarbonate less than 12mEq/L), and congenital disorders; newborns whose first dose of surfactant was administered later than 2 hours from birth; newborns who did not receive surfactant; newborns whose echocardiography revealed PDA symptoms; newborns who are under inotrope drugs administration; newborns whose cranial sonography suggested grade III to IV GM-IVH; newborns with air leak symptoms

Age

From **3 days** old to **14 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Isfahan University of Medical Sciences Ethics Committee

Street address

Faculty of Medicine, Isfahan University of Medical Sciences

City

Isfahan

Postal code**Approval date**

2015-01-20, 1393/10/30

Ethics committee reference number

394420

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

studying the brain tissue oxymetry

ICD-10 code

P52.2

ICD-10 code description

Intraventricular (nontraumatic) haemorrhage, grade 3, of fetus and newborn

Primary outcomes**1****Description**

brain tissue oxygenation

Timepoint

third day, seventh day, fourteenth day.

Method of measurement

Near Infrared Spectroscopy

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

intraventricular hemorrhage

Timepoint

daily

Method of measurement

transcranial sonography

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

Control Group: In this group, neonates are treated with nCPAP for two hours with two-hour intervals

Category

Treatment - Other

2**Description**

Intervention Group: In this group, neonates are treated with NIPPV for two hours with two-hour intervals

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr. Marzieh Zamani

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences-Vice
chancellery of Research and Technology

Full name of responsible person

Dr. Mehdi Nematbakhsh

Street address

Isfahan

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Sciences-Vice chancellery
of Research and Technology

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code
empty

Data Dictionary
empty