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 occurence 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

Name

Alireza Sadeghnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3335 1777

Email address

sadeghnia@med.mui.ac.ir

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 FiO2≥30% and CDP≥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 FiO2 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 echocardigraphy 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
intraventicular 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
Dr. Alireza Sadeghnia
Position
Assistant Professor
Other areas of specialty/work
Street address
Isfahan University of Medical Sciences, Isfahan
City
Isfahan
Postal code
Phone
+98 31 3335 1777
Fax
Email
asadeghnia@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr. Alireza Sadeghnia
Position
Assistant Professor
Other areas of specialty/work
Street address
Isfahan
City
Isfahan
Postal code
Phone
+98 31 3335 1777
Fax
Email
asadeghnia@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr. Alireza Sadeghnia
Position
Assistant Professor
Other areas of specialty/work
Street address
Isfahan
City
Isfahan
Postal code
Phone
+98 31 3335 1777
Fax
Email
asadeghnia@gmail.com
Web page address

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