Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

A comparison of 2 interventions for the Heated Humidified High Flow Nasal Cannula (HHHFNC) in preterm infants weighing 1000g to 1500g in the recovery period from newborns Respiratory Distress Syndrome (RDS)

Protocol summary

Summary

Abstract: Introduction: Nasal Cannula, which was first used to administer supplemental oxygen (Low Flow Therapy) in a large scale, also showed capability for the administration of CPAP through High Flow Nasal Cannula (HFNC). Needless to say, meeting specific physical criteria of %100 RH and temperature of 37oC are the basic interventional requirements to administer oxygen for the newborns airways through nasal cannula. Recently two systems, namely MR850 and PMH7000, were announced to maintain the FDA capabilities to administer HHHFNC. These systems were evaluated in this study In order to identify the appropriate system for administering HHHFNC based on their humidifying and heating capabilities. Methods and Materials: This study was done as an RCT on newborns weighing 1000g to 1500 g recovering from the RDS while nCPAP was administered at CDP=4 cm H2O, and Fio2<30%. Patients were randomized into two groups of 35 receiving HHHFNC after treatment with nCPAP, with one group taking advantage of MR850 Humidifier and the other using PMH7000. Patients were compared according to the duration of HHHFNC administration, repeated need for nCPAP respiratory support, the need for invasive ventilation, apnea, Chronic Lung Disease (CLD), nasal trauma, relative humidity and temperature of the gases. Results: The average time of support with HHHNFC didn't show any significant difference in two groups. There was no significant difference in the groups for the need for nCPAP, Invasive ventilation, apnea, nasal trauma, and CLD. The difference of the average temperature and humidity level was of significant difference (P-value<0.001). Conclusion: Although the records of temperature and relative humidity in PMH7000 system was lower than the records from MR850 system, no clinical priority was observed for respiratory support with HHHNFC in the two systems.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012092410430N3**
Registration date: **2013-05-24, 1392/03/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-05-24, 1392/03/03

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

2012-09-22, 1391/07/01

Expected recruitment end date

2013-03-21, 1392/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A comparison of 2 interventions for the Heated Humidified High Flow Nasal Cannula (HHHFNC) in preterm infants weighing 1000g to 1500g in the recovery period from newborns Respiratory Distress Syndrome (RDS)

Public title
Heated Humidified High Flow Nasal Cannula and RDS recovery in newborns
Purpose
Prevention
Inclusion/Exclusion criteria
Newborns receiving surfactant due to affiliation with RDS and their oxygen saturation was equal or more than 90% under nCPAP with CDP=4 cm H2O and FiO2<30% during the last 4 hrs, who still needed oxygen supplement after disconnection from nCPAP were included in the study; the exclusion criteria for this study were if there was a congenital malformation; prenatal asphyxia (min 5 apgar score equals 0 to 3, or umbilical cord pH less than 7, and the Bicarbonate level of the umbilical cord was reported to be less than 12), or nasal mucosa erythematic.
Age
From **1 year** old to **30 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Hezar Jerib St., Isfahan
City
Isfahan
Postal code
Approval date
2011-09-23, 1390/07/01
Ethics committee reference number
191140

Health conditions studied

1

Description of health condition studied
Newborn RDS
ICD-10 code
P22
ICD-10 code description
Respiratory distress of newborn

Primary outcomes

1

Description
Humidity
Timepoint
Every 6 hours
Method of measurement
Hygrometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: • For the newborns in the 7000PMH group the same procedure was applied except for the humidifying system for which the relative humidity and the temperature were set to 100% and 37oC at the end of the circuit, and also the temperature of the heater was set to 37 degrees while the temperature of the end probe was set to 40 degrees centigrade.
Category
Treatment - Devices

2

Description
Control Group: For the MR850 group newborns; first of all appropriate nasal cannula was provided which its diameter was not more than 50% of the newborn's nostril (11). Then the nasal cannula was attached to the specific circuit and was linked to the Chamber exit while the entrance of the chamber was adjusted by the blender through a pressure manifold. The humidifying system was attached to the circuit through the Heater Wire and temperature probes and the system was set to Invasive status.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Street address
City
Esfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. zohreh fallah
Street address
Faculty of Medicine, Esfahan University of Medical Sciences
City
Esfahan
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
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

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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