Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Continuous Positive Airway Pressure (CPAP) and Heated Humidified High Flow Nasal Cannula (HFNC) methods in treatment of neonates with respiratory distress syndrome with gestational age 28-34 weeks

Protocol summary

Study aim
comparing CPAP and HFNC in the treatment of RDS in premature infants with gestational age 28-34 weeks

Design
A randomised clinical trial, without blinding, without a control group, with parallel groups, 2 groups with 60 patients at each group

Settings and conduct
all eligible premature infants admitted to NICU of Ahvaz Imam Khomeini hospital in 1399, will receive respiratory support via HFNC or CPAP randomly.

Participants/Inclusion and exclusion criteria
Inclusion criteria: all premature infants admitted to NICU of Ahvaz, Imam Khomeini hospital with the gestational age of 28-34 weeks with RDS score<8 and valid parental consent. Exclusion criteria: major congenital anomaly, cyanotic congenital heart disease, neuromuscular disease, sepsis, congenital pneumonia, inborn errors of metabolism, meconium aspiration syndrome, perinatal asphyxia, APGAR score=< 5 at 5 minutes, intubation at birth or prolonged positive ventilation at delivery room, severe RDS necessitating intubation at birth based on NRP guidelines, severe cardiovascular instability, absence of spontaneous respiration and recurrent apnea, no respiratory distress

Intervention groups
Group 1: respiratory support via CPAP. Group 2: respiratory support via HFNC.

Main outcome variables
Efficacy of CPAP and HFNC methods in treatment of RDS in premature infants.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200616047788N1**
Registration date: **2020-07-21, 1399/04/31**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-21, 1399/04/31**
Update count: **0**

Registration date
2020-07-21, 1399/04/31

Registrant information

Name
Mohammad Reza Aramesh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3221 6501

Email address
aramesh-m@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2020-10-21, 1399/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Continuous Positive Airway Pressure

(CPAP) and Heated Humidified High Flow Nasal Cannula (HFNC) methods in treatment of neonates with respiratory distress syndrome with gestational age 28-34 weeks

Public title
Comparing two respiratory support methods in RDS treatment of premature neonates
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All preterm newborns with gestational age 28 -34 weeks, admitted to Imam Khomeini hospital, Ahvaz, 2020-2021
Exclusion criteria:
major congenital anomaly, cyanotic congenital heart disease, neuromuscular disease, sepsis, congenital pneumonia, inborn errors of metabolism, meconium aspiration syndrome, perinatal asphyxia, APGAR score=< 5 at 5 minutes, intubation at birth or prolonged positive ventilation at the delivery room, severe RDS necessitating intubation at birth based on NRP guidelines, severe cardiovascular instability, absence of spontaneous respiration and recurrent apnea, no respiratory distress.
Age
From **1 day** old to **7 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Cases will be divided into 2 groups based on random block permutations. random sequences will be obtained from www.sealedenvelope.com, section: create a randomization list then the patients admitted to the NICU will be divided to A & B groups as:
A,A,A,B,A,B,B,A,B,A,A,B,B....
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
Ethics committee of Ahvaz Jundishapur university of medical sciences
Street address
Golestan Blvd, Ahvaz, Iran
City
Ahvaz
Province
Khouzestan
Postal code
6193713956
Approval date
2020-06-07, 1399/03/18
Ethics committee reference number
IR.AJUMS.REC.1399.195

Health conditions studied

1

Description of health condition studied
neonatal respiratory distress syndrome
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
all premature infants with RDS sore <8
Timepoint
Rds score prior and after intervention
Method of measurement
Modified Downe's scoring system

Secondary outcomes

1

Description
need to intubation during first 72 hours of birth
Timepoint
third day of life
Method of measurement
physical examination, ABG, pulse oxymetry

2

Description
Intraventricular hemorrhage
Timepoint
from birth to discharge if complications associated with IVH appear (Anemia, a decrease of consciousness, change of vital signs)
Method of measurement
brain sonography

3

Description
chronic lung disease

Timepoint
day 28 of life
Method of measurement
need to Fio2> 21%

4

Description
patent ductus arteriosus requiring medical treatment
Timepoint
from 3rd to 7th day of life if symptoms associated with PDA appear(need to a higher fio2 , bounding pulses)
Method of measurement
echocardiography

5

Description
Air leak syndromes
Timepoint
from birth until receiving CPAP or HFNC
Method of measurement
physical examination, CXR

Intervention groups

1

Description
In the CPAP group we will use Fabian CPAP PLUS (Acutronic medical system, Switzerland) and Fisher & Paykel humidifiers (Auckland, News land). patients will receive positive end-expiratory pressure all day long until we can reduce fio2 to 30% and peep to 3 cmH2o.
Category
Treatment - Devices

2

Description
In the HFNC group we will use Sindi 1080 (medinSINDI® medical innovations, Germany) and Fisher & Paykel humidifiers (Auckland, News land) . patients will receive positive end-expiratory pressure all day long until we can reduce fio2 to 30% and flow to 3 lit/min.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
NICU of Ahvaz Imam Khomeini hospital
Full name of responsible person
Mohammad Reza Aramesh
Street address
Ahvaz, Imam Khomeini hospital
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
+98 61 3222 6104
Fax
+98 61 3222 6104
Email
aramaeshmr@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badvi
Street address
Ahvaz, Golestan blvd.
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8286
Email
info@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammd Reza Aramesh
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work

Pediatrics
Street address
Imam Khomeini hospital
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
+98 61 3222 6104
Email
Aramesh-m@ajums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Reza Aramesh
Position
associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Imam Khomeini hospital
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
0986132216502
Email
arameshmr@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad reza Aramesh
Position
associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Ahvaz, Imam Khomeini hospital
City
Ahvaz
Province
Khouzestan
Postal code
6193673116
Phone
+98 61 3221 6501
Email
aramesh-m@ajums.ac.ir

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