

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 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= $\leq$ 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)

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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= $\leq$ 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	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	<u>1</u> Description of health condition studied neonatal respiratory distress syndrome ICD-10 code ICD-10 code description
Primary outcomes	<u>1</u> 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	<u>1</u> Description need to intubation during first 72 hours of birth Timepoint third day of life Method of measurement physical examination, ABG, pulse oxymetry <u>2</u> 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 <u>3</u> 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, New Zealand). 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, New Zealand) . 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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

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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

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

Mohammad Reza Aramesh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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