Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

A comparative study of the response to Heated and Humidified High Flow Nasal Cannula treatment with Continuous Positive Airway Pressure method in premature infants with respiratory distress syndrome admitted to Qom Khairin Salamat Hospital

Protocol summary

Study aim
Comparison of the therapeutic response of Heated and Humidified High Flow Nasal Cannula (HHHFNC) with Continuous Positive Airway Pressure (CPAP) in premature infants admitted to Khairin Salamat Hospital, Qom

Design
An unblinded clinical trial with two randomized parallel groups using the permutation block method with 60 neonate sample

Settings and conduct
Randomly, neonate born in Khairin Salamat Qom hospital who have evidence of respiratory distress syndrome will be randomly divided into two groups, and one group will receive Heated and Humidified High Flow Nasal Canula and the other group will receive Continuous Positive Airway Pressure.

Participants/Inclusion and exclusion criteria
Evidence of respiratory distress syndrome in simple chest X-Ray, aged more than 28 weeks and less than 32 weeks, RDS Score at birth 4, 5, and 6, no surfactant reception

Intervention groups
Thirty infants in one group will receive warm and Humid High Flow Nasal Cannula, and another thirty infants will be ventilated with Continuous Positive Airway Pressure.

Main outcome variables
Improvement of respiratory distress syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231001059581N1**
Registration date: **2023-10-19, 1402/07/27**
Registration timing: **prospective**
Last update: **2023-10-19, 1402/07/27**
Update count: **0**

Registration date
2023-10-19, 1402/07/27

Registrant information

Name
Alireza Saadati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 25 3162 5100

Email address
asaadati@muq.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2024-01-10, 1402/10/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the response to Heated and Humidified High Flow Nasal Cannula treatment with Continuous Positive Airway Pressure method in premature infants with respiratory distress syndrome admitted to Qom Khairin Salamat Hospital

Public title

A comparative study of the response to Heated and Humidified High Flow Nasal Cannula treatment with Continuous Positive Airway Pressure method in premature infants with respiratory distress syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
RDS 4-6 Clinical sign Of RDS Gestational Age Between 28 To 32 Weight Less Than 1500g

Exclusion criteria:
Major Congenital Anomaly Asphyxia Sign Cyanotic Heart Disease Emergency Intubation

Age
From **1 day** old to **28 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To randomize people in two groups, permuted block randomization method of 4 is used. Considering two groups A and B, the randomization process will be as follows. The entire randomization file is available as an Excel file (randomization was done with SAS software version 9) Seed: 64404995453716 Block sizes: 4 Actual list length: 60 block identifier, block size, sequence within block, treatment • 1, 4, 1, Group B In this method, group A will receive HHHFNC treatment and group B will receive CPAP treatment. For example, the first neonate born will be placed in block number one, and according to the block sequence, it will sit in position number one, and according to the random data of the software will receive treatment B The first number is the block number, the second number is the block size and the third number is the block sequence

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
Research Ethics Committees of Qom University of Medical Sciences

Street address
No. 83, Lotfi Alley, Jahad Daneshghahi St., Safashahr St, Qom, Iran

City
Qom

Province
Ghoum

Postal code
9345637169

Approval date
2023-09-11, 1402/06/20

Ethics committee reference number
IR.MUQ.REC.1402.147

Health conditions studied

1

Description of health condition studied
Respiratory Distress Syndrome In Newborn

ICD-10 code
P22.0

ICD-10 code description
Respiratory distress syndrome of newborn

Primary outcomes

1

Description
RDS Score

Timepoint
From the beginning of the study, Every 4 hours until treatment or failure

Method of measurement
Downs scale Score

Secondary outcomes

1

Description
Need for intubation

Timepoint
Every 4 hours based on RDS score until treatment or failure

Method of measurement
Clinical examination, RDS score

2

Description
Treatment duration

Timepoint
Every 4 hours based on RDS score until treatment or failure

Method of measurement
Day

Intervention groups

1

Description
First Intervention group: Neonate In The First Group Receive Oxygen With A Continuous Pressure Of 5 To 6 Cm Of Water And A Flow Rate Of 8 To 10 By CPAP.
Category
Treatment - Devices

2

Description
The Second Intervention group: In This Group, Neonate Receive Air With A Temperature Of 37 Degrees And Humidified With An Average Volume Of 2750 cc Per Minute (Neonate Weighing Less Than 1000 Grams Will Receive 2500 cc Of Air Per Minute And Neonate Weighing More Than 1000 Grams Will Receive 3000 cc Of Air Per Minute).
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Khaerin Salamat Hospital
Full name of responsible person
Alireza Saadati
Street address
Qom, Delazar St
City
Qom
Province
Ghoum
Postal code
3715873355
Phone
+98 25 3133 3000
Email
Nekoeihospital@muq.ac.ir

2

Recruitment center
Name of recruitment center
Fatemeh Masoumeh Hospital
Full name of responsible person
Alireza Saadati
Street address
Imam Khomeini St
City
Qom
Province
Ghoum
Postal code
3719815539
Phone
+98 25 3665 1801
Email
Hospital-masumeh@muq.ac.ir

3

Recruitment center
Name of recruitment center
Shohada Hospital
Full name of responsible person
Alireza Saadati
Street address
North Hekmat, Tohid Blvd
City
Qom
Province
Ghoum
Postal code
3717994544
Phone
+98 25 3110 0000
Email
shohada@muq.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Dr. Rahim Aali
Street address
Shahid Lavasani (Saheli) St., Qom, I.R. Iran
City
Qom
Province
Ghoum
Postal code
3716993456
Phone
+98 25 3285 4011
Email
int_office@muq.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Alireza Saadati
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Imam KhomeniSt ,Qom
City
Qom
Province
Ghoum
Postal code
3713649373
Phone
+98 25 3162 5100
Fax
Email
asaadati@muq.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Alireza Saadati
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Imam KhomeniSt ,Qom
City
Qom
Province
Ghoum
Postal code
3713649373
Phone
+98 25 3162 5100
Fax
Email
asaadati@muq.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Alireza Saadati
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Imam KhomeniSt ,Qom
City
Qom
Province
Ghoum
Postal code
3713649373
Phone
+98 25 3162 5100
Fax
Email
asaadati@muq.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