

# 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 Cannula 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 Daneshgahi St., Safashahr St, Qom, Iran

#### **City**

Qom

#### **Province**

Ghous

#### **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**

Ghoush University of Medical Sciences

**Full name of responsible person**

Alireza Saadati

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ghoush University of Medical Sciences

**Full name of responsible person**

Alireza Saadati

**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Ghoush University of Medical Sciences

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**Position**

Assistant Professor

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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