

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparing two methods of cannula nasal with high flow and conventional Fio2 for successful weaning of preterm infants with respiratory distress from Nasal CPAP in Alzahra and Shahidbeheshti hospitals, Isfahan

#### Protocol summary

##### Summary

In this randomized clinical trial, two groups of preterm infants (each group contains 44 infants, gestational age 28-37 weeks) with respiratory distress syndrome (RDS) in NICU of Al-Zahra or Shahid-Beheshti hospitals who are on the Nasal Continuous Positive Airway Pressure (NCPAP) with P=5 CmHg and Fio2≤30% at least for 6 hours, in stable state (respiratory rate<60, without pulmonary resuscitation, having no apnea and bagging, having less than 6 apnea episodes) will be studied. Written informed consent will be obtained from parents. Then we randomly allocate infants into two groups; HHFNC group (Humidified High Flow Nasal Cannula) who dissent from NCPAP at Fio2≤30% and receive 2 Lit/min O2 via cannula nasal, control group who are continued to the NCPAP till Fio2=21% to achieve a stable condition for 24 hours. In HHFNC group, O2 is adjusted according to infant need to maintain the O2 arterial pressure between 87 and 92%. The O2 flow is not changed till Fio2=21%, then its flow will decrease each 6 hours to achieve 0.5 L/min and at this time infant will be departed. To maximize the efficacy, prong size will be appropriate to infant's nose. Successful weaning is considered when infant could be stable for 72 hours in the room temperature. Statistical analysis will be conducted using SPSS version 20, independent t-test, and chi-square test will be used to test significant differences between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014012716376N1**  
Registration date: **2014-02-08, 1392/11/19**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-02-08, 1392/11/19

##### Registrant information

###### Name

Alireza Eshghi

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1625 5555

###### Email address

ali\_phd203@yahoo.com

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

##### Expected recruitment start date

2012-04-20, 1391/02/01

##### Expected recruitment end date

2014-02-19, 1392/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing two methods of cannula nasal with high flow and conventional Fio2 for successful weaning of preterm infants with respiratory distress from Nasal CPAP in Alzahra and Shahidbeheshti hospitals, Isfahan

##### Public title

Comparing two methods of cannula nasal with high flow and conventional Fio2 for successful weaning of preterm infants with respiratory distress from Nasal CPAP in Alzahra and Shahidbeheshti hospitals, Isfahan

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

Inclusion criteria: preterm infants with respiratory distress syndrome (RDS) and gestational age (28-37 weeks) who require NCPAP; being stable on NCPAP at Fio2≤30% for 6 hours; no clinical sign of RDS such as tachypnea, severe apnea, intercostals retraction and nasal flaring. Exclusion criteria: infants with genetic anomalies; congenital cyanotic heart disease; genetic anomalies in airways or chest; pulmonary hypoplasia; genetic neurologic disease; neuro-muscular disease; inter ventricular hemorrhages (grade 3-4) and hydrocephaly.

#### **Age**

From **28 years** old to **37 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **88**

#### **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**

Ethics Committee of Isfahan University of Medical Sciences

###### **Street address**

Isfahan University of Medical Sciences, Hezar Jarib St., Isfahan

###### **City**

Isfahan

###### **Postal code**

73461-8174

##### **Approval date**

2010-09-23, 1389/07/01

##### **Ethics committee reference number**

390620

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Respiratory distress syndrome

##### **ICD-10 code**

P22.0

##### **ICD-10 code description**

Respiratory distress syndrome of newborn

### **Primary outcomes**

#### **1**

##### **Description**

Apnea

##### **Timepoint**

From the time on the Nasal Continuous Positive Airway Pressure (NCPAP) till departing from O2

##### **Method of measurement**

Observation

#### **2**

##### **Description**

Duration of need for respiratory support

##### **Timepoint**

From the time on the Nasal Continuous Positive Airway Pressure (NCPAP) till departing from O2

##### **Method of measurement**

Observation

#### **3**

##### **Description**

Duration of O2 treatment

##### **Timepoint**

From the time on the Nasal Continuous Positive Airway Pressure (NCPAP) till departing from O2

##### **Method of measurement**

Observation

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group (Humidified High Flow Nasal Cannula group) who dissent from NCPAP at Fio2≤30% and receive 2 Lit/min O2 via cannula nasal

##### **Category**

Treatment - Other

#### **2**

##### **Description**

Control group: who are connected to the NCPAP at

Fio2=21% to achieve a stable condition for 24 hours.

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Alzahra hospital

**Full name of responsible person**

Dr. Alireza Eshghi

**Street address**

Sofeh st., Isfahan

**City**

Isfahan

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Isfahan University of Medical Sciences

**Full name of responsible person**

Dr. Peyman Adibi

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib St., Isfahan

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Isfahan 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**

**Contact**

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Eshghi

**Position**

MD, Resident of pediatrics

**Other areas of specialty/work**

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**Full name of responsible person**

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**Position**

Specialist in pediatrics

**Other areas of specialty/work**

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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*