

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

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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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Position

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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