

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Nasal intermittent positive pressure ventilation with nasal cannula vs. Nasal continuous positive airway pressure as respiratory support in the management of Transient Tachypnea of Newborn: A Randomized Control Trial

Protocol summary

Study aim

To investigate the efficacy of NIPPV with nasal cannula vs. NCPAP as respiratory support in the management of Transient Tachypnea of Newborn

Design

This study is a parallel randomized clinical trial. Our sample size is 40 people, 20 people will be in each group. In this method, a number of cards are considered as the first group and the same number of cards for the next group. Then, by merging the cards together, a card is taken out and its allocation is recorded. And that card will be returned to the other cards after leaving.

Settings and conduct

This double-blinded randomized clinical trial will be done in the neonatal department at Shariati Hospital of Tehran, from June 2021 through August 2021. We will choose neonates with moderate respiratory distress (Downes score 4-5) who have the inclusion criteria of TTN but underwent randomization. The intervention group will receive NIPPV as respiratory support, and the other group receives CPAP. We will monitor every neonate with pulse oximetry and cardiac monitoring, recording oxygen consumption (rate of FiO₂), and the total duration of the specified respiratory support in both groups.

Participants/Inclusion and exclusion criteria

All of the neonates were born 37 weeks and older. Neonates with TTN were identified with the criteria of Rawlings and Smith. Exclusion criteria were; neonate delivered less than 37 weeks, significant chromosomal abnormalities, meconium aspiration signs, asphyxia, a newborn baby with a metabolic disorder, congenital heart disease, persistent pulmonary hypertension of neonate, RDS, Pneumonia, and requirement of more than 40 percent FiO₂. We excluded neonates who had positive CRP or positive Blood culture or if chest x rays matched

with the diagnosis of pneumonia.

Intervention groups

NIPPV may be applied by nasal cannula to intervention group

Main outcome variables

oxygen consumption duration of respiratory support

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210607051507N1**

Registration date: **2021-07-01, 1400/04/10**

Registration timing: **retrospective**

Last update: **2021-07-01, 1400/04/10**

Update count: **0**

Registration date

2021-07-01, 1400/04/10

Registrant information

Name

Ameneh Lamsehchi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01
Expected recruitment end date
 2021-06-27, 1400/04/06
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Nasal intermittent positive pressure ventilation with nasal cannula vs. Nasal continuous positive airway pressure as respiratory support in the management of Transient Tachypnea of Newborn: A Randomized Control Trial

Public title
 Nasal intermittent positive pressure ventilation with nasal cannula vs. Nasal continuous positive airway pressure as respiratory support in the management of Transient Tachypnea of Newborn

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Neonates with TTN were identified with the criteria of Rawlings and Smith including 1. beginning of tachypnea within 6 h after birth; 2. tenacity of tachypnea for at least 12 h; 3. chest radiograph compatible with TTN 4. exclusion of other known respiratory disorders and non-respiratory disorders likely to cause the same features. Clinical features consist of tachypnea (respiratory rate more than 60) with or without cyanosis, signs of distress (nasal flaring, grunting, and retraction). Radiographic signs may include at least one of these; lung hyperinflation, perihilar congestion or streaking, fluid filled interlobar fissure, bilateral infiltration, pulmonary edema. All of the neonates were born 37 weeks and older.
Exclusion criteria:
 neonate delivered less than 37 weeks, significant chromosomal abnormalities, meconium aspiration signs, asphyxia, a newborn baby with a metabolic disorder, congenital heart disease (diagnosed with echocardiography), persistent pulmonary hypertension of neonate, RDS, Pneumonia, and requirement of more than 40 percent FiO2. We excluded neonates who had positive CRP or positive Blood culture or if chest x rays matched with the diagnosis of pneumonia.

Age
 No age limit

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **40**
Randomization (investigator's opinion)
 Randomized
Randomization description
 This study is a parallel randomized clinical trial that will be performed on neonates of Shariati Hospital of Tehran University of Medical Sciences. Our sample size is 40 people, 20 people will be in each group. In this method, a number of cards are considered as the first group and the same number of cards for the next group. Then, by merging the cards together, a card is taken out and its allocation is recorded. And that card will be returned to the other cards after leaving. The cards are then merged again and another card comes out. This process continues until a random sequence according to the sample size is reached.

Blinding (investigator's opinion)
 Double blinded
Blinding description
 Concealment process: The list of random allocation of patients will be available only to the epidemiologist of the project. To hide the random allocation process, the order of interventions will be written on 40 cards and each card will be placed in an envelope (with a suitable thickness that it is not possible to read the type of intervention on the cover of the envelope). When the interviewer declares a baby eligible, the methodologist will provide the group with a plan for the type of intervention. The person evaluating the intended outcomes is a third party who is unaware of the random allocation process and the type of treatment performed. For data analysis, a statistician who is separate from the study process and is unaware of all the processes performed will be used.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees
1
Ethics committee
Name of ethics committee
 Tehran University of medical sciences
Street address
 Enghelab street. Ghods Ave.
City
 tehran
Province
 Tehran
Postal code
 1417613151
Approval date
 2020-04-30, 1399/02/11
Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Transient Tachypnea of Newborn

ICD-10 code

ICD-10 code description

□Intermittent Positive Pressure Ventilation ,
Nasal Continuous Positive Airway Pressure,
Transient Tachypnea of Newborn

Primary outcomes

1

Description

oxygen consumption

Timepoint

24 hours of birth

Method of measurement

CPAP .NIPPV

2

Description

the duration of respiratory support

Timepoint

during hospitalization

Method of measurement

due to records patients file

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:NIPPV may be applied by a facial mask or nasal cannula. In this study, we used a nasal cannula to deliver positive-pressure breathing by Drager (Babylog 8000 SC) ventilator with flow constant (flow =8).

Category

Treatment - Devices

2

Description

O2 therapy with CPAP. with prong and 8-10 flow

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

the neonatal department at Shariati Hospital of Tehran

Full name of responsible person

Setareh Sagheb

Street address

Tehran, North Kargar St., Jalal Al-Ahmad Intersection, Shariati Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Deputy of research and technology

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Grant name

Grant code / Reference number

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

No

Title of funding source

Tehran university of medical sciences

Proportion provided by this source

1

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

Tehran University of Medical Sciences

Full name of responsible person

Setareh Sagheb

Position

MD. Assistant Professor of Neonatology.

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Tehran University of Medical Sciences

Full name of responsible person

ameneh lamsehchi

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available