Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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)

Phone
+98 21 6656 1315

Email address
lamsehchila@gmail.com

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:

N eonates 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 are 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 hyper inflation, 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

IR.TUMS.MEDICINE.REC.1399.040

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 pronge 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
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Email
lamsehchila@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Deputy of research and technology
Street address
Enghelab street. Ghods Ave
City
tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 6405 3334
Email
okazi@tums.ac.ir
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

Street address
Shariati Hospital

City
Tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 8490 1000

Email
dr.ssagheb@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
ameneh lamsehchi

Position
MD. Pediatrician

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

Street address
Shariati Hospital

City
Tehran

Province
Tehran

Postal code
1411713135.

Phone
+98 21 8490 1000

Email
lamsehchila@gmail.com

Person responsible for updating data

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
Subspecialist

Other areas of specialty/work
Pediatrics

Street address
Shariati Hospital

City
Tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 8490 1000

Email
dr.ssagheb@yahoo.com

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