

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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 FiO<sub>2</sub>), 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 FiO<sub>2</sub>. 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:**  
 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 FiO<sub>2</sub>. 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

##### 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