

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### **A comparative study on the effect of using nasal protector (Neo-Guard) on the incidence rate and severity of nasal injury in preterm infants treated with Nasal-Continuous Positive Airway Pressure**

#### **Protocol summary**

##### **Study aim**

A comparative study on the effect of using nasal protector (Neo-Guard) on the incidence rate and severity of nasal injury in preterm infants treated with Nasal-Continuous Positive Airway Pressure

##### **Design**

A randomized controlled clinical trial with parallel groups, single blind, randomized blocking method in two 40-person groups

##### **Settings and conduct**

This study will be performed in the NICU section of Alzahra and Shahid Beheshti Hospital in Isfahan. At first we receive written informed consent from the parents of the newborns. After convenience sampling, random allocation will be done using blocking method (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>). Considering the sample size, there will be 40 neonate in each group. A list of letters A and B will be drawn at random from the four blocks using the software. Neonates in group (A) will receive Neo-Guard and infants in group (B) will receive routine care. Neonates in both groups will be monitored and evaluated every 12 hours to 72 hours after treatment with N-CPAP.

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria 1-Premature infants 32 weeks or less or premature infants weighing 1500 g or less who require N-CPAP 2-Parents of infants consent to study for infants  
Exclusion criteria 1-Premature infants who are >32 weeks of postmenstrual age (PMA) or Premature infants(<37 weeks(PMA)) at a weight <1500 g 2-The infant was intubated before receiving N-CPAP and received invasive ventilation 3-Preterm infants who had facial features that might preclude treatment with binasal CPAP (eg, cleft lip, Pierre Robin sequence, choanal atresia)

##### **Intervention groups**

The intervention group will be treated with Neo-Guard

and the control group will receive routine care.

##### **Main outcome variables**

The scale of incidence of nasal injury; Severity of nasal injuries; N-CPAP failure rate

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20191217045769N1**

Registration date: **2020-03-15, 1398/12/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-15, 1398/12/25**

Update count: **0**

##### **Registration date**

2020-03-15, 1398/12/25

##### **Registrant information**

##### **Name**

Soheila Jafari

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 31 3670 0196

##### **Email address**

jafari.soheila@gmail.com

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2019-12-31, 1398/10/10

##### **Expected recruitment end date**

2020-04-29, 1399/02/10

##### **Actual recruitment start date**

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

#### **Scientific title**

A comparative study on the effect of using nasal protector (Neo-Guard) on the incidence rate and severity of nasal injury in preterm infants treated with Nasal-Continuous Positive Airway Pressure

#### **Public title**

Effect of neogard protection to reduce nasal injury in preterm infants receiving N-CPAP

#### **Purpose**

Prevention

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

##### **Inclusion criteria:**

Premature infants 32 weeks or less or premature infants weighing 1500 g or less who require N-CPAP Parents are satisfied with the baby's entry into the study.

##### **Exclusion criteria:**

Premature infants who are >32 weeks of postmenstrual age (PMA) or Premature infants(<37 weeks(PMA)) at a weight <1500 g The infant was intubated before receiving N-CPAP and received invasive ventilation Preterm infants who had facial features that might preclude treatment with binasal CPAP (eg, cleft lip, Pierre Robin sequence, choanal atresia)

#### **Age**

To **8 months** old

#### **Gender**

Both

#### **Phase**

N/A

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

- Participant

#### **Sample size**

Target sample size: **80**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

We first identify each group with a letter such as Group A (Intervention Group), Group B (Control Group) and thus two groups will be named A and B. Each research unit is assigned a number, and depending on the sample size, a list of 80 neonates will be obtained, each grouping 40 neonates. with using the software and considering the four blocks a list of letters A and B will be randomly generated . Then they will be assigned to one of the groups by list and arrival arrange

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

Because the participants are newborns

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Deputy of research and technology-Isfahan University of Medical Sciences

##### **Street address**

Hezar Jarib Street, Isfahan, Iran

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

81746-73461

#### **Approval date**

2019-11-05, 1398/08/14

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

IR.MUI.RESEARCH.REC.1398.415

## **Health conditions studied**

### 1

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

Nasal injury associated with N-CPAP in preterm infants

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

P07.3

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

Preterm [premature] newborn [other]

## **Primary outcomes**

### 1

#### **Description**

Incidence and severity of nasal injury

#### **Timepoint**

Every 12 hours to 72 hours

#### **Method of measurement**

Check list

## **Secondary outcomes**

### 1

#### **Description**

N-CPAP failure or success rate

#### **Timepoint**

Time of removing neonatal from N-CPAP

#### **Method of measurement**

Check list

## **Intervention groups**

## 1

### Description

Intervention group will use neoguard nasal protector to prevent nasal injury

### Category

Prevention

## 2

### Description

Control group will receive routine care.

### Category

Prevention

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Alzahra and Shahid Beheshti Hospital of Isfahan

#### Full name of responsible person

Soheila Jafari-Mianaei

#### Street address

Hezar jarib street, isfahan, iran

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174643446

#### Phone

+98 31 3792 7595

#### Email

m\_jafari@nm.mui.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Soheila jafari mianaei

#### Street address

Hezar jarib street, Isfahan

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174673461

#### Phone

+98 31 3792 9595

#### Email

m\_jafari@nm.mui.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Esfahan University of Medical Sciences

#### Proportion provided by this source

100

#### 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

Esfahan University of Medical Sciences

#### Full name of responsible person

Soheila Jafari-Mianaei

#### Position

Assistant Professor of Pediatric and neonatal Department, School of Nursing and Midwifery

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Pediatrics

#### Street address

Hezar jarib street, Isfahan

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174643446

#### Phone

+98 31 3792 7595

#### Email

m\_jafari@nm.mui.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Soheila Jafari-Mianaei

#### Position

Assistant Professor of Pediatric and Neonatal Department, School of Nursing and Midwifery

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Pediatrics

#### Street address

Isfahan Hezar Jerib Street

#### City

Isfahan

#### Province

Isfahan  
**Postal code**  
8174643446  
**Phone**  
+98 31 3792 7595  
**Email**  
m\_jafari@nm.mui.ac.ir

8174643446  
**Phone**  
+98 31 3670 0196  
**Fax**  
**Email**  
jafari.soheila@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Soheila Jafari-Mianaei  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
Sofeh Blvd,School of Nursing and Midwifery, Isfahan  
University of Medical Sciences,group infant  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**

## 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

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

### Analytic Code

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

### Data Dictionary

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