# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Comparison of Bubble CPAP with Variable CPAP in respiratory distress syndrome in preterm infants

## Protocol summary

**Summary**

Respiratory distress syndrome is the most common cause of death in premature infants. One of the methods used in the treatment of neonatal respiratory distress syndrome is a continuous positive airway pressure. This is a randomized clinical trial was performed on 40 premature infants. The study population were preterm infants (34-28 weeks gestation) admitted in neonatal intensive care unit of the Shahid Sadoghi hospital. 20 people numbers were calculated for each group of infants was randomly allocated to either the intervention group (Bubble CPAP) or control (Variable CPAP). Respiratory condition, including duration of continuous positive airway pressure, duration of mechanical ventilation and duration of oxygen therapy was considered as the primary outcome.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2014081918862N1**
Registration date: **2014-09-27, 1393/07/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2014-09-27, 1393/07/05

**Registrant information**

**Name**

Mohsen Karimi

**Name of organization / entity**

Shahid Sadoughi University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

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**Recruitment status**

**Recruitment complete**

**Funding source**

Shahid Sadoughi University of Medical Sciences

**Expected recruitment start date**

2013-04-05, 1392/01/16

**Expected recruitment end date**

2014-03-11, 1392/12/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of Bubble CPAP with Variable CPAP in respiratory distress syndrome in preterm infants

**Public title**

Continuous positive airway pressure in premature infants with respiratory distress syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Gestational age of 28-34 weeks; Birth weight 1000-2400 g; Respiratory distress syndrome; Respiratory score 5-7 under the Table Silverman Anderson Exclusion criteria: Infants with congenital malformations including congenital heart disease, congenital diaphragmatic hernia, esophageal atresia, cleft lip and palate, Gastrochesia, emphalocele and gastrointestinal obstruction ; Moderate to severe asphyxia (II,III); Clinical signs of infection; Hematocrit less than 35; ICH , IVH (III.IV); Lack of parental consent

**Age**

To **1 year** old

**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **40**
**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 Shahid Sadoughi University of Medical Sciences
**Street address**
Shahid Sadoughi University of Medical Sciences, Shahid Bahonar Square, Yazd
**City**
Yazd
**Postal code**
**Approval date**
2014-01-07, 1392/10/17
**Ethics committee reference number**
259875

## Health conditions studied

**1**

**Description of health condition studied**
respiratory distress syndrome of preterm neonates
**ICD-10 code**
P22
**ICD-10 code description**
Respiratory distress syndrome of newborn

## Primary outcomes

**1**

**Description**
Duration of CPAP
**Timepoint**
12 to 24 hour and during daily visits
**Method of measurement**
PEEP Pressure , Fio2

**2**

**Description**
Duration of mechanical ventilation
**Timepoint**
12 to 24 hour and during daily visits
**Method of measurement**
PIP , Fio2 , PEEP , RR

**3**

**Description**
Duration of Oxygen with Hood
**Timepoint**
12 to 24 hour and during daily visits
**Method of measurement**
Fio2

## Secondary outcomes

**1**

**Description**
incidence of complications ( IVH,PDA,Pneumothorax)
**Timepoint**
Daily until discharge
**Method of measurement**
IVH with brain sonography, PDA with echocardiography,Pneumothorax with CXR or transilumination

**2**

**Description**
Weight gain at discharge
**Timepoint**
Daily until discharge
**Method of measurement**
scale

**3**

**Description**
Duration of Hospitalization
**Timepoint**
Daily until discharge
**Method of measurement**
date

**4**

**Description**
Death
**Timepoint**
Daily until discharge
**Method of measurement**
Physical exam

## Intervention groups

### 1

**Description**
CPAP by under water Bubble CPAP system (Fisher & Paykel Healthcare, Auckland 2013 Panmure, Auckland 1741 New Zealand)
**Category**
Treatment - Devices

### 2

**Description**
NCPAP with Medijet (Medijet active NCPAP Generator, Medin Innovations GmbH Lindberghstrasse Ikaruspark D - 82178 Puchheim)
**Category**
Treatment - Devices

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shahid Sadoughi Hospital
**Full name of responsible person**
Dr Mahmood Noori Shadkam - Neonatalogist
**Street address**
Shahid Sadoughi Hospital, Avenue Ibn Sina, Shahid Ghandi Boulevard, Atlasi Square, Yazd
**City**
Yazd

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Shahid Sadoughi University of Medical Sciences
**Full name of responsible person**
Dr.Fatemah Ezoddini
**Street address**
Shahid Sadoughi University of Medical Sciences Central Building, Shahid Bahonar Square, Yazd
**City**
Yazd
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shahid Sadoughi 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**
Shahid Sadoughi University of Medical Sciences
**Full name of responsible person**
Dr Mohsen Karimi
**Position**
Pediatrics Assistant
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*