

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Early nasal intermittent positive pressure ventilation versus continuous positive airway pressure in preterm infants with respiratory distress syndrome

Protocol summary

Summary

The aim of this study was to compare the prognosis and side effects in premature neonates with gestational age between 28 to 34 weeks at Fatemiyeh Hospital affiliated to Hamedan University of Medical Science with respiratory distress syndrome that are treated with nasal intermittent positive pressure ventilation or nasal continuous positive airway pressure. This clinical trial was performed on sixty premature neonates with birth weight between 1000 to 2000 grams with respiratory distress within 6 hours of birth and 2 or more of symptoms of respiratory distress or Silverman-Anderson score of 6 or 7 were eligible and patients are classified into 2 groups. The subjects were randomly assigned in two groups to receive early nasal continuous positive airway pressure and early nasal intermittent positive pressure ventilation. All newborns were observed for seven days about the need for mechanical ventilation, adverse outcomes and death. In these time pneumothorax, patent ducts steroids (PDA), lung hemorrhage, disseminated intravascular coagulopathy (DIC), icterus, sepsis was determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072618598N1**

Registration date: **2015-09-25, 1394/07/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-09-25, 1394/07/03

Registrant information

Name

Mohamad Kazem Sabzehei

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3823 2803

Email address

mk.sabzehei@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Early nasal intermittent positive pressure ventilation versus continuous positive airway pressure in preterm infants with respiratory distress syndrome

Public title

Comparison of non-invasive treatment through the nose for the treatment of respiratory immaturity in preterm neonates

Purpose

Treatment

Inclusion/Exclusion criteria

All consecutively born preterm infants with gestational

age between 28 to 34 weeks, admitted to Fatemiyeh neonatal intensive care unit with respiratory distress syndrome Inclusion criteria: approved RDS; gestational age between 28 to 34 weeks; neonates with 72 hours age after delivery. Exclusion criteria: the neonates with APGAR score less than 3 at five minutes after birth; those whom mother had rupture of the membrane for more than three weeks; severe malformation; chromosomal anomalies such as trisomy of 13, 18 and 21; pneumonia; pneumothorax

Age

From **1 day** old to **1 day** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary IDs**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Hamedan University of Medical Sciences

Street address

Hamedan university of medical science, Daneshgah street, Pajohesh square

City

Hamedan

Postal code**Approval date**

2014-11-25, 1393/09/04

Ethics committee reference number

4201/9/35/16/پ

Health conditions studied**1****Description of health condition studied**

treatment

ICD-10 code

p22, p22.0

ICD-10 code description

Respiratory distress of newborn

Primary outcomes**1****Description**

survival rates in 7 days

Timepoint

during hospitalization and using NIPPV and NCPAP

Method of measurement

comparing survival rates

Secondary outcomes**1****Description**

need to mechanical ventilation

Timepoint

during hospitalization and using NIPPV and NCPAP

Method of measurement

during hospitalization and using NIPPV and NCPAP

2**Description**

lung hemorrhage

Timepoint

during hospitalization and using NIPPV and NCPAP

Method of measurement

during hospitalization and using NIPPV and NCPAP

3**Description**

pneumothorax

Timepoint

during hospitalization and using NIPPV and NCPAP

Method of measurement

during hospitalization and using NIPPV and NCPAP

4**Description**

NEC

Timepoint

during hospitalization and using NIPPV and NCPAP

Method of measurement

during hospitalization and using NIPPV and NCPAP

5**Description**

sepsis

Timepoint

during hospitalization and using NIPPV and NCPAP

Method of measurement

during hospitalization and using NIPPV and NCPAP

6

Description

mortality

Timepoint

during hospitalization and using NIPPV and NCPAP

Method of measurement

during hospitalization and using NIPPV and NCPAP

Intervention groups

1

Description

Using of early nasal continuous positive airway pressure at least 48 hours with the maximum positive end expiratory pressure: 5 cmH₂o and Fio₂: 60%

Category

Treatment - Other

2

Description

Using of early nasal intermittent positive pressure ventilating at least 48hours with the maximum PEEP: 5 cmH₂o, Fio₂: 60%, PIP: 16 cmH₂o, Resirstory rate: 30/min

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemiyeh Hospital

Full name of responsible person

Maryam Nasresfahani

Street address

Hamedan University of Medical Sciences, Daneshgah street, Pajohesh square

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Mohamad Yosef Alikhani

Street address

Daneshgah street, Pajohesh square, Hamedan

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Mohamad Kazem Sabzehei

Position

Neonatologist-assistant professor

Other areas of specialty/work

Street address

Fatemiyeh Hospital, Kermanshah street, Hamedan

City

Hamedan

Postal code

Phone

+98 81 3838 0749

Fax

Email

Mk_sabzehei@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamdan University of Medical Sciences

Full name of responsible person

Mohamad Kazem Sabzehei

Position

Neonatologist- assistant professor

Other areas of specialty/work

Street address

Fatemiyeh Hospital, Kermanshah street, Hamedan

City

Hamedan

Postal code

Phone

+98 81 3838 0749

Fax

Email

Mk_sabzehei@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Science

Full name of responsible person

Mohamad Kazem Sabzehei

Position

Neonatologist- assistant professor

Other areas of specialty/work**Street address**

Fatemiyeh Hospital, Kermanshah street, Hamedan

City

Hamedan

Postal code**Phone**

00

Fax**Email**

Web page address

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