Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of two level of pressure support ventilation on success of extubation in preterm neonates

Protocol summary

Summary

The purpose of this randomized clinical trial is to investigate the effect of two level of pressure support ventilation on success of extubation in preterm neonates. We include 30 preterm neonates between 27-37 weeks of gestation who are under mechanical ventilation and ready for extubation in Pressure Support (PSV) mode. The intervention under study is extubation the neonates with two different level of pressure support 10 and 6 CmH2o respectively in two groups . Extubation Failure during 48 hours after extubation as the primary outcome of our study will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201309302801N3**
Registration date: **2014-06-20, 1393/03/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-06-20, 1393/03/30

Registrant information

Name

Roya Farhadi

Name of organization / entity

Mazandaran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Mazandaran university of Medical Science

Expected recruitment start date

2013-11-01, 1392/08/10

Expected recruitment end date

2014-12-01, 1393/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two level of pressure support ventilation on success of extubation in preterm neonates

Public title

level of pressure support ventilation on success of extubation in preterm neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all neonates 27-37 weeks gestation; under mechanical ventilation at least 48 hours due to RDS; is in Weaning Phase. Exclusion Criteria: Pneumothorax; congenital anomalies; meconium aspiration pneumonia; congenital heart disease;asphyxia

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

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
Mazandaran University Of Medical Sciences
Street address
Vice chancellor research, Mazandaran University of Medical Sciences, Moallem street
City
Sari
Postal code
4817844718
Approval date
2014-03-05, 1392/12/14
Ethics committee reference number
399-14-12-92

Health conditions studied

1

Description of health condition studied
Extubation failure
ICD-10 code
P28.5
ICD-10 code description
Respiratory failure of newborn

Primary outcomes

1

Description
Extubation failure
Timepoint
48 hours after intervention
Method of measurement
observation

Secondary outcomes

1

Description
Death
Timepoint
72 hours after extubation
Method of measurement
observation

2

Description
pneomotorax
Timepoint
72 hours after extubation
Method of measurement
observation

3

Description
weaning time
Timepoint
from biginning of PSV mode till extubation point
Method of measurement
observation & documentation

4

Description
tidal volume
Timepoint
3 times during PSV mode till extubation
Method of measurement
internal measurement by ventilator device

5

Description
work of breathing
Timepoint
3 times during PSV mode till extubation
Method of measurement
internal measurement by ventilator device

6

Description
dynamic compliance
Timepoint
3 times during PSV mode till extubation
Method of measurement
internal measurement by ventilator device

Intervention groups

1

Description
Intervention 1:Extubation from mechanichal ventilator while neonates receive 10 CmH2O of Pressure in Pressure Support mode/
Category

Treatment - Devices

2

Description
Intervention2: Extubation from mechanichal ventilator while neonates receive 6 CmH2O of Pressure in Pressure Support mode
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Boo Ali-Sina Hospital
Full name of responsible person
Roya Farhadi
Street address
Pasdaran bulevard-Boo Ali-Sina Hospital
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati
Street address
Vice chancellor research, Mazandaran University of Medical Sciences, Moallem street, Sari
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Mazandaran 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
Mazandaran University Of Medical Sciences
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Assistant professor/ Neonatologist
Other areas of specialty/work
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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