

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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

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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

pneumotorax

Timepoint

72 hours after extubation

Method of measurement

observation

3

Description

weaning time

Timepoint

from beginning 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 mechanical ventilator
while neonates receive 10 CmH2O of Pressure in
Pressure Support mode/

Category

Treatment - Devices

2

Description

Intervention2: Extubation from mechanical 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 boulevard-Boo Ali-Sina Hospital

City

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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

Full name of responsible person

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Position

Assistant professor/ Neonatologist

Other areas of specialty/work

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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