Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Efficacy of positive pressure during removal of endo tracheal tube on prevention of post extubation atelectasis in ventilated neonates

Protocol summary

Summary

The purpose of this randomized clinical trial is to investigate the effect of positive pressure during extubation of oro-tracheal ventilated neonates in prevention of post extubation atelectasis. We include 53 neonates who are under oro-teracheal mechanical ventilation for at least 24 hours and are ready for extubation. The intervention under study is extubation the neonates with positive pressure by T-Piece Resuscitator connected to endotracheal tube. In control group neonates will extubate with negative pressure as a conventional method by suction catheter of endotracheal tube. Post extubation atelectasis in CXR of 4 and 24 hours after extubation is investigated as the primary outcome in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112092801N2**
Registration date: **2011-12-29, 1390/10/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-12-29, 1390/10/08

Registrant information

Name

Roya Farhadi

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3334 3018

Email address

rfarhadi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

vice chancellor research of Mazandaran University of Medical Sciences

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of positive pressure during removal of endo tracheal tube on prevention of post extubation atelectasis in ventilated neonates

Public title

Effect of positive pressure on prevention of post extubation atlectasis in neonates

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all neonates under oro-teracheal mechanical ventilation at least for 24 hours and are ready to extubation. Exclusion criteria are: 1-neonates suffer from broncho- pulmonary dysplasia; 2-Congenital anomaly of head and neck and thoracic cavity; 3-Naso-teracheal intubation; 4-Symptomatic PDA in echocardiography; 5- Congenital neuromuscular disorders; 6-IVH grade 3, 4; 7-Asphixia.

Age

To **1 year** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **53**
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
Mazandaran University Of Medical Sciences
Street address
Vice chancellor research, Mazandaran University of Medical Sciences, Moallem street
City
Sari
Postal code
4817844718
Approval date
2011-11-09, 1390/08/18
Ethics committee reference number
90-113

Health conditions studied

1

Description of health condition studied
atelectasis
ICD-10 code
J98.1
ICD-10 code description
Pulmonary collapse

Primary outcomes

1

Description
atelectasis
Timepoint
4 annd 24 hours after extubation
Method of measurement
observation of chest X ray

Secondary outcomes

1

Description
extubation Failure
Timepoint
during 48 hours after extubation
Method of measurement
observation

2

Description
Apnea
Timepoint
during 72 hours after extubation
Method of measurement
observation and respiratory monitoring

3

Description
pneomothoraxs
Timepoint
during 72 hours after extubation
Method of measurement
Chest x ray

Intervention groups

1

Description
Intervention: Removal of endotheracheal tube with positive pressure by a T-Piece Resusciator connected to endotheracheal tube regulated
Category
Prevention

2

Description
Control: Removal of endotheracheal tube with negative pressure with suction of endotheracheal tube during Extubation (100 mmHg)
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Boo Ali Sina Hospital
Full name of responsible person
Roya Farhadi
Street address

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
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
Roya Farhadi
Position
Assistant Professor, Neonatologist
Other areas of specialty/work
Street address
BooAli Sina Hospital
City
Sari
Postal code
Phone
+98 15 1223 3011
Fax
Email
dr.royafarhadi@gmail.com , rfarhadi@mazums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Roya Farhadi
Position
Assistant professor, Neonatologist
Other areas of specialty/work
Street address
BooAli Sina Hospital
City
Sari
Postal code
Phone
+98 15 1223 3011
Fax
Email
dr.royafarhadi@gmail.com , rfarhadi@mazums.ac.ir
Web page address

Person responsible for updating data

Contact

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