

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Public title

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

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all neonates under oro-tracheal 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-tracheal intubation; 4-Symptomatic PDA in echocardiography; 5- Congenital neuromuscular disorders; 6-IVH grade 3, 4; 7-Asphyxia.

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 and 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

pneomothorax

Timepoint

during 72 hours after extubation

Method of measurement

Chest x ray

Intervention groups

1

Description

Intervention: Removal of endotracheal tube with
positive pressure by a T-Piece Resuscitator connected to
endotracheal tube regulated

Category

Prevention

2

Description

Control: Removal of endotracheal tube with negative
pressure with suction of endotracheal 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