Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of neonatal mortality and morbidity after separation from ventilator by positive pressure, suction and non-intervention methods

Protocol summary

Study aim
Comparison of neonatal mortality and morbidity after separation from ventilator by positive pressure, suction and non-intervention methods

Design
A double-blind randomized clinical trial with parallel and control groups, Phase 2, involving 65 neonates, 38% in the positive pressure intervention and negative pressure suction groups (19 in each group), and 27 in the spontaneous octopus

Settings and conduct
in tube newborns in Ayatollah Taleghani in Ilam, who have the necessary conditions to be extubated, will enter in positive pressure, suction with negative pressure, and spontaneous extubation. The study was double-blind and the intervention infants and evaluators were unaware of the type of allocation in the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria 1- All newborns who are connected to a ventilator and have an order of extubation 2-Written informed consent of parents Exclusion criteria 1- All newborns with congenital anomalies

Intervention groups
Intervention group 1: Separation of neonates from ventilator using positive pressure ventilation method, Intervention group 2: Separation of neonates from ventilator using negative pressure suction method and control group: Spontaneous separation

Main outcome variables
Co2 pressure,re-insertion of endotracheal intubation,Re-need for artificial ventilation,extensive atelectasis, increased respiratory effort

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110523006575N6**
Registration date: **2021-09-18, 1400/06/27**
Registration timing: **retrospective**

Last update: **2021-09-18, 1400/06/27**
Update count: **0**

Registration date
2021-09-18, 1400/06/27

Registrant information

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Name of organization / entity
Ilam University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-11, 1400/02/21

Expected recruitment end date
2021-09-12, 1400/06/21

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of neonatal mortality and morbidity after separation from ventilator by positive pressure, suction and non-intervention methods

Public title

Comparison of neonatal mortality and morbidity after separation from ventilator by positive pressure, suction and non-intervention methods

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All newborns who connected to a ventilator and have an order of ventilator separation

Exclusion criteria:

Congenital anomalies

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **65**

Randomization (investigator's opinion)

Randomized

Randomization description

19 cards with the title of intervention 1, 19 cards with the title of intervention 2, and 27 cards with the title of control will be placed in 65 envelopes of the same shape. The envelopes are placed irregularly and one envelope is opened for each newborn from one side

Blinding (investigator's opinion)

Double blinded

Blinding description

Newborns will not have an understanding of the type of intervention. Extubation in positive pressure support, negative pressure suction and the automatically group will be done without the presence of evaluators. Documents will be registered in 3 groups A, B, C. Evaluators will record the results of the study only on a group basis and without knowing the type of allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of]مشئ University of Medical Sciences

Street address

Pajouhesh Blvd, Faculty of Nursing and Midwifery, Ilam University of Medical Sciences, Ilam, Iran

City

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Province

Ilam

Postal code

6939177143

Approval date

2021-05-10, 1400/02/20

Ethics committee reference number

IR.MEDILAM.REC.1400.014

Health conditions studied

1

Description of health condition studied

Comparison of neonatal mortality and morbidity after separation from ventilator by positive pressure, suction and non-intervention methods

ICD-10 code

ICD-10 code description

Weaning

Primary outcomes

1

Description

Re-intubation

Timepoint

Regularly during the treatment period

Method of measurement

Documentation File

2

Description

Mortality

Timepoint

Regularly during the treatment period

Method of measurement

Documentation File

3

Description

Pneumothorax

Timepoint

Regularly during the treatment period

Method of measurement

Chest radiography

4

Description

Oxygen saturation

Timepoint

Regularly during the treatment period

Method of measurement

Pulse oximeter

5

Description
Duration of hospitalization
Timepoint
Regularly during the treatment period
Method of measurement
Documentation File

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Positive pressure support, with expanding ammo bag and squeezing ambos 3-4 times, will slowly separate
Category
Treatment - Devices

2

Description
Intervention group: Suction with a pressure of 100-80 mm Hg to which the N.G tube is connected will be used. At the same time as the negative pressure is applied, the endotracheal tube will be pulled out
Category
Treatment - Devices

3

Description
Control group: Spontaneous extubation
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani Hospital, Ilam University of Medical sciences, Ilam, Iran
Full name of responsible person
Dr. Sajad Nourolahi
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ilam University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Dr. Ashraf Direkvand-Moghadam
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available