

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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

Name

Ashraf Direkvand-Moghadam

Name of organization / entity

Ilam University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 84 3222 7134

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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 [مشرف] University of Medical Sciences

Street address

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

City

Ilam

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 Nouroloahi

Street address

Ayatollah Taleghani Hospital, Shahid Beheshti Boulevard, Ilam, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Dr.Mohammad Reza Kaffashian

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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

Position

Associate Professor of Reproductive Health, Department of Midwifery, Faculty of Nursing and Midwifer

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Dr. Sajad Nourolahi
Position
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Person responsible for updating data

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Other areas of specialty/work

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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