

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Effect of using respirometer during cardiopulmonary resuscitation on quality of neonatal cardio pulmonary resuscitation and Pneumotorax Incidence

Protocol summary

Summary

This study is about using of respirometer during resuscitation on quality of cardiopulmonary resuscitation of infants and the incidence of pneumothorax. Objectives of this study involves comparing a First minute Apgar, Five minute Apgar , expiratory tidal volume, respiratory rate and incidence of pneumothorax after resuscitation in both usual resuscitation groups by use of respirometer. This study is a quasi-experimental,before and afterone group,Single-blind and the study population are the infants in need of resuscitation at birth in Ghaem hospital. sample size is 30 pation in each group . Inclusion criteria contain baby who has heart rate less than 100 per minute after first steps of resuscitation and based on a preliminary assessment and needs to have a bag-valve ventilation reduction with intervention and Exclusion criteria are babies who need to cardiac massage for continuing resuscitation . Intervention is that the newborn baby in the operating room after the first steps resuscitation,if he or she has a heart rate less than 100 per minute ,ventilation with bag-valve mask should be started and connected to respirometer and then number and exhaled tidal volume is recorded so that reviver cant be able to view the ventilation parameters. In the next step after the sampling in this group completed, again ventilation volume and its number by respirometer is recorded in newborns require resuscitation during ventilation with bag-valveas required ,so that reviver can be able to view the ventilation parameters and amend it. Intervention time is about 4 months .Consequences of this study is incidence of pneumothorax after resuscitation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092224139N1**

Registration date: **2016-02-13, 1394/11/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-13, 1394/11/24

Registrant information

Name

Samaneh Eftekhari Salmanian

Name of organization / entity

Mashad University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 51 3501 8517

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eftekhar1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Mashhad University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of using respirometer during cardiopulmonary resuscitation on quality of neonatal cardio pulmonary resuscitation and Pneumotorax Incidence

Public title

The effect Of ventilation monitoring on the quality of Neonatal resuscitation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: baby's first steps after resuscitation and heart rate less than 100 per minute, based on a preliminary assessment and the need to have a bag-valve ventilation reduction with intervention and exclusion criteria is the baby who needs to cardiac massage.

Age

From **1 day** old to **1 day** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad. School of Nursing and Midwifery

City

Mashhad

Postal code

iran

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

931782

Health conditions studied

1

Description of health condition studied

Cardiopulmonary resuscitation

ICD-10 code

I46.0

ICD-10 code description

Cardiac arrest with successful resuscitation

Primary outcomes

1

Description

exhaled tidal volume

Timepoint

Before and after feedback feedback

Method of measurement

with respirometer

2

Description

The number of ventilation per minute

Timepoint

Before and after feedback feedback

Method of measurement

with respirometer

3

Description

First minute Apgar

Timepoint

Before and after feedback feedback

Method of measurement

Recorded in the check list

4

Description

Fifth minute Apgar

Timepoint

Before and after feedback feedback

Method of measurement

Recorded in the check list

5

Description

Pneumothorax

Timepoint

Before and after feedback feedback

Method of measurement

Clinical symptoms and chest x-ray and the doctor confirmed

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Put respirometer at the junction of the mask and bag-valve mask During neonatal resuscitation with respirometer feedback to Reviver

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital.

Full name of responsible person

samane eftekhsalmanian

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City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Mashhad University of Medical Sciences

Full name of responsible person

Gavade malekzade

Street address

School of Nursing

City

Mashhad

Grant name

931782

Grant code / Reference number

931782

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research,Mashhad 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

Mashhad University Of Medical Sciences

Full name of responsible person

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Position

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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