Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Eftekhar Salmanian

Name of organization / entity

Mashad University of Medical Science

Country

Iran (Islamic Republic of)

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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
exhalled 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 eftekharsalmanian
Street address
Mshhad.mlm 82 No. 1
City
Mshhad

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
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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
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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