

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of open and closed endotracheal tube suctioning system on Cardio-respiratory parameters of infants undergoing mechanical ventilation in Isfahan's selected hospital on 2010

Protocol summary

Summary

This study aimed to evaluate effect of open and closed suctioning methods on respiratory parameters of infants undergoing mechanical ventilation. Materials and Methods: In this crossover clinical trial, 44 infants were selected among those undergone mechanical ventilation in NICU of Isfahan's Al-Zahra Hospital using convenience sampling method. inclusion criteria were met: lack of neurological-muscle diseases, congenital heart diseases and its resulted impairment; and lack of active bleeding, fever, endotracheal intubation and mechanical ventilation exclusion criteria were met: extubation , blood transfusion, change in ventilator setting. The subjects were randomly divided into two groups. In the first group, open suctioning was carried out and after three hours of cleaning, closed suctioning was done. In the second group, closed suctioning was firstly done and following three hours of cleaning, open suctioning was implemented. Respiratory rate (RR) and percentage of arterial blood oxygen saturation and respiratory rate was measured 3 minutes before, during and immediately after and 3 minutes after each type of suctioning.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013040612908N1**
Registration date: **2013-04-28, 1392/02/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-04-28, 1392/02/08

Registrant information

Name

Narges Asgari

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Isfahan University of Medical Sciences

Expected recruitment start date

2010-05-05, 1389/02/15

Expected recruitment end date

2011-01-22, 1389/11/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of open and closed endotracheal tube suctioning system on Cardio-respiratory parameters of infants undergoing mechanical ventilation in Isfahan's selected hospital on 2010

Public title

Effect of closed and open suctioning on Cardio-respiratory parameters

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria were met: lack of neurological-muscle diseases, congenital heart diseases and its resulted impairment; and lack of active bleeding, fever, endotracheal intubation and mechanical ventilation exclusion criteria : extubation , blood transfusion, change in ventilator setting

Age

To **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jirib street, Azadi square, Isfahan

City

Isfahan

Postal code

Approval date

2009-12-22, 1388/10/01

Ethics committee reference number

12/11/5679/پ

Health conditions studied

1

Description of health condition studied

Cardio-respiratory parameters

ICD-10 code

p07.0, p0

ICD-10 code description

Extremely low birth weight dysmaturity - small(ness)-fetus or newborn for gestational age

Primary outcomes

1

Description

Blood pressure

Timepoint

2 minute before, during and 2 minute after suctioning

Method of measurement

Intensive care monitor

2

Description

Arterial blood oxygen saturation

Timepoint

3minute before, during,immediatly after and 3 minute after suctioning

Method of measurement

Pulse oximetry

3

Description

Pulse rate

Timepoint

3minute before, during,immediatly after and 3 minute after suctioning

Method of measurement

Pulse oximetry

4

Description

Respiratory rate

Timepoint

3minute before, during,immediatly after and 3 minute after suctioning

Method of measurement

Ventilator

Secondary outcomes

empty

Intervention groups

1

Description

In this study , the open suction is done on the samples. In this way, the neonate separated from the ventilator and suction catheter placed inside the tracheal tube and suction is done.

Category

Prevention

2

Description

Again the open suctioning in the same patient was performed after 3 hours closed suctioning is done. in this way the catheter placed in the ventilatory circuit and the

possibility of suctioning performed without removing the patient from the ventilator

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan AL-Zahra Hospital

Full name of responsible person

Narges Asgari

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Narges Asgari

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Isfahan University of Medical Sciences, Hezar Jirib
Street, Azadi Square, Isfahan

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Narges Asgari

Position

MSc. pediatric nursing

Other areas of specialty/work

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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