Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of two methods open and closed endotracheal suctioning on clinical outcomes in preterm neonates in NICUs of Alzahra and Taleghani Teaching Hospitals, Tabriz, 2012

Protocol summary

Summary

This study is a single blind clinical trial in order to compare clinical outcomes of two methods open and closed endotracheal suctioning. A population of preterm neonates with 27-34 weeks of gestational age born at Alzahra and Taleghani hospitals of Tabriz are to be studied; whom after their admission to NICU they are intubated with in maximum 24 hours and will be under mechanical ventilation at least for 48 hours. After verifying sample size, the neonates are elected by available simple sampling method and randomly divided between two study groups. First group will be suctioned by open and second suctioned by closed method. In both groups, suctioning as PRN and will be continued for atlleast48 hours. BP, HR, O2SAT in both groups should be recorded one minute before and one and five minutes after procedure, and registered in the special data forms designed by research team. However frequency of suctioning and side effects as pulmonary hemorrhage, IVH, pneumothorax, pneumonia and septicemia until extubation and as well as duration of hospitalization. Side effects should be confirmed by a specialist who is blind to suction kind. Finally the above mentioned results will be compared for both groups. Analysis of data is to be done by using SPSS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204078315N3**
Registration date: **2012-05-13, 1391/02/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-05-13, 1391/02/24

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source
Tabriz University of Medical Sciences

Expected recruitment start date
2012-05-14, 1391/02/25

Expected recruitment end date
2012-10-21, 1391/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of two methods open and closed endotracheal suctioning on clinical outcomes in preterm neonates in NICUs of Alzahra and Taleghani Teaching Hospitals, Tabriz, 2012

Public title

Effect of endotracheal suctioning on clinical outcomes in preterm neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Preterm neonates of 27-34 weeks of gestational age born at Alzahra and Taleghani hospitals whom are admitted at NICU. 2- After maximum 24 hours of their admission to NICU are intubated due to the respiratory distress. 3- Neonates receiving surfactant. 4- Preterm neonates who are ventilated for at least 48 hours. 5- Neonates without congenital anomalies or heart diseases. 6- Neonates without MAS. 7- PROM less than 18 hours and 8- Neonates with less than 3 times of intubation trial. Exclusion criteria: 1- Neonates with proved immune deficiency. 2- Neonates who are referred to other centers before completion of data and 3- Neonates whose congenital heart disease and ... is verified later.

Age

To **10 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz Medical Sciences Ethic Committee

Street address

Golgasht St.Tabriz University of Medical Sciences

City

Tabriz

Postal code

Approval date

2012-03-12, 1390/12/22

Ethics committee reference number

913

Health conditions studied

1

Description of health condition studied

Evaluation of suction effect

ICD-10 code

J70.9

ICD-10 code description

Respiratory conditions due to unspecified external agent

Primary outcomes

1

Description

Verification and comparison of physiological stability

Timepoint

Befor one minute and after one minute and after five minute

Method of measurement

By the use of Monitoring

2

Description

Number of suctioning needed

Timepoint

Duration of time from first suctioning till extubation

Method of measurement

Data record form

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

Untill discharch from NICU

Method of measurement

Data record form

2

Description

Side effects of suctioning

Timepoint

From 24 after first suctioning till extubation

Method of measurement

By use of data record form

Intervention groups

1

Description

In closed group tracheal sactioning will be continued for atlleast48 huors. BP,HR,O2SAT should be recorded one minute before and one and five minutes after procedure,How ever frequency of suctioning and side effects as polmunary hemorage, IVH, penomotorax, ponomonia and septisemy until extubation and as well as duration of hospitalization registered in the special data

forms .

Category

Treatment - Other

2

Description

In open group tracheal sactioning will be continued for atlleast48 huors. BP,HR,O2SAT should be recorded one minute before and one and five minutes after procedure,How ever frequency of suctioning and side effects as polmunary hemorage, IVH, penomotorax, ponomonia and septisemy until extubation and as well as duration of hospitalization registered in the special data forms .

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra teaching hospitals

Full name of responsible person

Rahele Janani

Street address

Str. Southern Artesh, Baghshmal

City

Tabriz

2

Recruitment center

Name of recruitment center

Talegani teaching hospitals

Full name of responsible person

Rahele Janani

Street address

Rahahan st.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Tabriz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Reza Rashidi

Street address

Azadi Street - Street Golgasht - Tabriz University of Medical Sciences

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Tabriz 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