

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Influence of lateral and supine position on bacterial colonization of endotracheal tube in neonates were admitted in neonatal intensive care unit of 17 shahrivar hospital of Rasht: A comparison

Protocol summary

Summary

The aim of this study is to investigate the effect of supine and lateral position on bacterial colonization of endotracheal tube in neonates. Thirty four neonates with gestational age ≥ 28 weeks from the last menstrual period, who do not have congenital malformations such as tracheoesophageal fistulae, chest deformities or diaphragmatic hernia that need to intubation within 48 hours of birth will be enrolled and randomly divided into two groups: group A(neonates in supine position) and B(neonates in lateral position). Demographic data and the results of routine laboratory tests will be recorded. Neonates with congenital sepsis or pneumonia and who cannot be maintained on mechanical ventilation for 5 full days will be excluded. Group A will be maintained on their backs and endotracheal tube held upright in a vertical position (routine care in our NICU) and group B subjects will be positioned on their sides (left or right) with the back supported by a rolled soft towel and endotracheal tube held in horizontal position. Researcher will culture tracheal secretions in the second and fifth days of mechanical ventilation for both groups. A single microbiologist blind to the grouping will analyze the dishes and will do the antibiogram study. Then we will compare the results of laboratory tests and bacterial colonization between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202199075N1**

Registration date: **2012-03-30, 1391/01/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-03-30, 1391/01/11

Registrant information

Name

Seyyedeh Zohreh Jalali

Name of organization / entity

Guilan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 13 1324 5126

Email address

z_jalali@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2010-03-02, 1388/12/11

Expected recruitment end date

2011-03-31, 1390/01/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Influence of lateral and supine position on bacterial colonization of endotracheal tube in neonates were admitted in neonatal intensive care unit of 17 shahrivar hospital of Rasht: A comparison

Public title

Influence of position on bacterial colonization of endotracheal tube in neonates

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Gestational age ≥ 28 weeks from the last menstrual period; tracheal intubation at postnatal age of <48 hours; absence of congenital malformations such as tracheoesophageal fistulae, chest deformities or diaphragmatic hernia. Exclusion criteria: congenital sepsis or pneumonia and mechanical ventilation less than full 5 days.

Age

To 2 years old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 34

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

Vice chancellor for research, Guilan University of Medical Sciences

Street address

5 Km of Tehran road, Rasht

City

Rasht

Postal code

Approval date

2009-12-21, 1388/09/30

Ethics committee reference number

1880508504

Health conditions studied

1

Description of health condition studied

Bacterial colonization due to intubation

ICD-10 code

T81.4

ICD-10 code description

Infection following a procedure, not elsewhere classified

2

Description of health condition studied

Bacterial colonization due to intubation

ICD-10 code

T81.9

ICD-10 code description

Unspecified complication of procedure

Primary outcomes

1

Description

Bacterial colonization of endotracheal tube

Timepoint

Second and fifth days of intubation

Method of measurement

Culture of endotracheal secretions

Secondary outcomes

empty

Intervention groups

1

Description

Interventional group (group B or lateral group): In this group, neonates will be positioned on their sides with the back supported by a rolled soft towel and endotracheal tube held in horizontal position. They alternatively will be rotated to left or right lateral position by trained nurses every two hours.

Category

Prevention

2

Description

The control group (group A or supine group) will be maintained on their backs and their endotracheal tubes held upright in a vertical position (routine care in our NICU).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

17 Shahrivar hospital

Full name of responsible person

Seyyedeh Zohreh Jalali

Street address

In front of the Azodi stadium, Namju avenue, Rasht
City
Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Tchnology, Guilan
University of Medical Sciences

Full name of responsible person

Abdolrasul Sobhani

Street address

First floor, In front of Alzahra hspital, Mellat street,
Namju avenue,Rasht

City

Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research and Tchnology, Guilan
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**

Guilan University of Medical Science

Full name of responsible person

Seyyede Zohreh Jalali

Position

Neonatologist/Assistant Professor

Other areas of specialty/work**Street address**

17 Shahrivar hospital, In front of Azodi stadium,
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City

Rasht

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+98 13 1322 9524

Fax**Email**

zj5722003@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Guilan University of Medical Science

Full name of responsible person

Seyyede Zohreh Jalali

Position

Neonatologist/Assistant Professor

Other areas of specialty/work**Street address**

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Person responsible for updating data

Contact**Name of organization / entity**

Guilan University of Medical Science

Full name of responsible person

Fatemeh Aghamahdi

Position

MD

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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