

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 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  $\geq 28$  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  $\geq$  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**  
Seyyedeh Zohreh Jalali

**Position**  
Neonatologist/Assistant Professor

**Other areas of specialty/work**

**Street address**  
17 Shahrivar hospital, In front of Azodi stadium,  
Namju avenue, Rasht

**City**  
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**Postal code**

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+98 13 1322 9524

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zj5722003@yahoo.com

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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MD

**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*