

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jul 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 atleast 48 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

###### Name

Leila Valizadeh

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1479 6770

###### Email address

valizadehl@tbzmed.ac.ir

##### 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**

Before one minute and after one minute and after five minutes

### **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**

Until discharge 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 suctioning will be continued for at least 48 hours. BP, HR, O2SAT should be recorded one minute before and one and five minutes after procedure. However frequency of suctioning and side effects as pulmonary hemorrhage, IVH, pneumothorax, pneumonia and sepsis until extubation and as well as duration of hospitalization registered in the special data

forms .  
**Category**  
Treatment - Other

## 2

### Description

In open group tracheal suctioning will be continued for atleast 48 hours. BP, HR, O2SAT should be recorded one minute before and one and five minutes after procedure, However frequency of suctioning and side effects as pulmonary hemorrhage, IVH, pneumothorax, pneumonia and sepsis 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**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
rahele janani  
**Position**  
MS nursing Student  
**Other areas of specialty/work**  
**Street address**  
Tabriz Faculty of Nursing and Midwifery, South Shariati Street  
**City**  
Tabriz  
**Postal code**  
00984114796770  
**Phone**  
+98 41 1328 0465  
**Fax**  
**Email**  
rahele\_janani@yahoo.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Dr Leila Valizadeh  
**Position**  
Professor assistant  
**Other areas of specialty/work**  
**Street address**  
Tabriz Faculty of Nursing and Midwifery, South Shariati Street  
**City**  
Tabriz  
**Postal code**  
**Phone**  
+98 41 1479 6770  
**Fax**  
+98 41 1479 6969  
**Email**  
valizadehl@tbzmed.ac.ir

**Web page address**

+98 41 1328 0465

## Person responsible for updating data

**Email**

rahele\_janani@yahoo.com

**Web page address**

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Raheleh Janani

**Position**

MS Nursing Student

**Other areas of specialty/work**

**Street address**

Tabriz Faculty of Nursing and Midwifery, South Shariati  
Street

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1328 0465

**Fax**

## 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*