

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### N-acetylcysteine for endotracheal tube patency in neonates: A randomized clinical trial

#### Protocol summary

##### Summary

We performed this study to evaluate the effect of intratracheal administration of N-acetylcysteine (NAC) on clinical status and adverse effect of intubation in neonates with RDS. This double-blind randomized controlled trial was conducted on 65 neonates admitted to NICU ward of Rasoul-Akram hospital, Tehran, Iran. They were mechanically ventilated with clinical and radiological evidence of chronic lung disease and respiratory distress syndrome. They were divided into 2 groups: one consisted of 29 neonates receiving tracheal administration of 5% NAC and the other consisted of 36 neonates receiving saline placebo. Number of tracheal tube exchange (time to exchange) and hemorrhage were recorded in groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138810012420N2**

Registration date: **2010-02-10, 1388/11/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-02-10, 1388/11/21

##### Registrant information

###### Name

Seyed-Mohammad Fereshtehnejad

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2275 6035

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mohammad@stu.iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Iran University of Medical Sciences

##### Expected recruitment start date

2003-03-20, 1381/12/29

##### Expected recruitment end date

2005-03-20, 1383/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

N-acetylcysteine for endotracheal tube patency in neonates: A randomized clinical trial

##### Public title

The effect of N-acetylcystein in outcome and adverse effects of intubation in neonates

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion Criteria: Neonates > 1200 gram hospitalized in NICU of Rasoul Akram hospital and needed to be intubated and mechanically ventilated based on standard protocols. Exclusion Criteria: Neonates with major anomalies or cyanotic cardiac diseases, neonates who ere intubated at the beginning of their hospitalization, neonates with pneumothorax at the time of hospitalization or intubation, massive hemorrhage, neonates who were extubated before 24 hours or dead before this time

##### Age

To **1** year old

##### Gender

Both

**Phase**  
N/A

**Groups that have been masked**  
No information

**Sample size**  
Target sample size: 65

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Iran University of Medical Sciences and Health services

##### Street address

Iran University of Medical Sciences and Health services, Hemmat highway

##### City

Tehran

##### Postal code

14155-5983

##### Approval date

2006-07-10, 1385/04/19

##### Ethics committee reference number

2217

## Health conditions studied

### 1

#### Description of health condition studied

Respiratory Distress Syndrome of neonates

#### ICD-10 code

P22.0

#### ICD-10 code description

Respiratory distress syndrome of newborn

## Primary outcomes

### 1

#### Description

The duration of first intubation until exchange of endotracheal tube due to mucus plug retention

#### Timepoint

every 6 hours

#### Method of measurement

Tube cleaning with drugs in order to make sure that it's open

## Secondary outcomes

### 1

#### Description

number of endotracheal tube obstruction and replacement due to mucus plug

#### Timepoint

every 6 hours

#### Method of measurement

cleaning of the endotracheal tube to make sure that it's open

### 2

#### Description

duration of intubation

#### Timepoint

every day

#### Method of measurement

observation

### 3

#### Description

events those may be related to the new drug including apnoea and bradycardia, hypotension, pulmonary haemorrhage

#### Timepoint

every 6 hours

#### Method of measurement

monitoring of the patient

### 4

#### Description

death

#### Timepoint

every 6 hours

#### Method of measurement

control of vital signs

## Intervention groups

### 1

#### Description

cleaning of the endotracheal tube every 6 hours with 2 milliliter of N-acetylsuccine solution

#### Category

Other

### 2

#### Description

cleaning of the endotracheal tube every 6 hours with 2

mililiter of normal saline solution  
**Category**  
Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Rasoul Akram Hospital  
**Full name of responsible person**  
**Street address**  
**City**  
Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Vice chancellor for research, Iran University of  
Medical Sciences and Health Services  
**Full name of responsible person**  
Azita Zabihi  
**Street address**  
Hemmat highway  
**City**  
Tehran  
**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, Iran University of Medical  
Sciences and Health Services  
**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**  
Iran University of Medical Sciences and Health  
Servuces  
**Full name of responsible person**  
Seyyed Mohammad Fereshteh Nejad

**Position**  
MD  
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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Rasoul Akram Hospital  
**Full name of responsible person**  
Parisa Mohagheghi  
**Position**  
Pediatrician, Neonetologist  
**Other areas of specialty/work**  
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Rasoul Akram Hospital, Niayesh street, Sattarkhan  
avenue  
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pmohagh@yahoo.com  
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## Person responsible for updating data

### Contact

## 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*