# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Jun 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
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**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: Neovates > 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**
Respiratoty 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 endotracheak 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 mililiter of N-acetylsucteine solution
**Category**
Other

### 2

**Description**
cleaning of the endotracheal tube every 6 hours with 2

milliliter 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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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Rasoul Akram Hospital

**Full name of responsible person**

Parisa Mohagheghi

**Position**

Pediatrician, Neonetalogist

**Other areas of specialty/work**

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**Web page address**

## 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*