

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Pro-inflammatory cytokine profile of intubated patients following nebulization of hypertonic saline as prophylaxis of VAP

Protocol summary

Summary

As study of effect of nebulization of hypertonic saline 5% in intubated patients for prevention of ventilatory associated pneumonia, in a randomized controlled double blind clinical trial, 30 patients, 20-60 yr, male and female, divided to two groups, intervention group, nebulization NaCl 5% (n=15), control group, sterile water (n=15). Inclusion criteria: intubation period less than 24 hour, no clinical and imaging manifestation of pneumonia exclusion criteria: pulmonary infection; Acute physiology and chronic health evaluation II score II > 25; active infection in admission; evidence of infection in chest X ray; immune deficiency; prescribe of high dose corticosteroid (more than 300mg hydrocortisone); advanced cancer. In intervention group hypertonic saline 5%, 7 ml and in control group water sterile, 7 ml, will be nebulized until extubation or for 7 days each 6 hour. Before start of study (phase 0) and 48, 72, 120 and 144 hour sample of tracheal secretions and blood will be provided for microbial smear and culture and Interleukin-6, Potassium, Sodium, blood gas analysis, blood sugar, blood urea, Creatinin, hemoglobin, hematocrit, Acute Physiology And Chronic Health Evaluation II score, Simplified clinical Pulmonary Infection score will be measured and recorded. we will record age, gender, cause of ICU admission and comorbidity too.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202169045N1**
Registration date: **2015-09-01, 1394/06/10**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-09-01, 1394/06/10

Registrant information

Name

Mohammad Taghi Beigmohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2511

Email address

beigmohammadi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-01-19, 1394/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pro-inflammatory cytokine profile of intubated patients following nebulization of hypertonic saline as prophylaxis of VAP

Public title

inflammatory profile following nebulization of hypertonic saline as prophylaxis of VAP

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: intubation period less than 24 hour, no

clinical and imaging manifestation of pneumonia
exclusion criteria: pulmonary infection; Acute physiology and chronic health evaluation II score II>25; active infection in admission; evidence of infection in chest X ray; immune deficiency; prescribe of high dose cortocosteroid (more than 300mg hydrocortisone); advanced cancer.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

Tehran University of Medical Sciences

Street address

Teran, Keshavarz st., forward of ghods st.

City

Tehran

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

90-02-30-11653-42368

Health conditions studied

1

Description of health condition studied

Ventilatory Associated Pneumonia

ICD-10 code

J67-J70

ICD-10 code description

Aspiration pneumonia (due to): NOS, food, (regurgitated)
gastric secretions, milk, vomit

Primary outcomes

1

Description

pneumonia

Timepoint

0, 48, 72, 120 and 144 hour after start of study.

Method of measurement

physical exam,chest x ray, culture of tracheal secretion

Secondary outcomes

1

Description

level of Interlukin- 6 levelof trachea secretions and blood

Timepoint

0, 48,72,120 and 144 hour after start of study

Method of measurement

ELIZA

Intervention groups

1

Description

in intervention group 7 ml hypertonic saline 5% and in control group 7 ml sterile water will be nebulized each 6 hours until the extubated or maximum for 7 days. The patients will be followed for 28 days and 28 days mortality rate will record.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex ICUs

Full name of responsible person

Dr. Mohammad Taghi Beigmohammadi

Street address

Imam Khomeini Hospital Complex

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Seyed Ahmad Rezaii

Street address

Keshavarz street, edge of ghods street, Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

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