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 nebolization of hypertonic saline 5% in intubated patients for prevention of ventilatory associated pneumonia, in a randimized controlled double blind clinical trial,30 patients, 20-60 yr, male and female, divided to two groups, intervention group, nebolization NaCl5% (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 cortocosteroid (more than 300mg hydrocortisone); advanced cancer. In intervention group hypertonic saline% ,7 ml and in control group water sterile, 7 ml, will be nebolized 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 Interlukin-6. Potassium,Sodium, blood gas analysis, blood suger, blood urea, Creatinin, hemoglubin, hematocrit,Acute Physiology And Chronic Health Evaluation II score, Simlified clinical Pulmonary Infectious score will be meassured and recorded. we will record age, gender, cause of ICU addmision 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

Assisstant Professor

Other areas of specialty/work

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Web page address

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