

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of Nebulized Budesonide and Intravenous Dexamethasone on Tracheal Tube Cuff Leak in Intubated Patients Admitted to Intensive Care Unit

Protocol summary

Summary

The aim of this study was to compare effects of nebulized Budesonide and intravenous dexamethasone on tracheal tube cuff leak in intubated patients admitted to intensive care unit. The study included 270 patients admitted to ICU, aged between 18-65 years with the history of 48 hours intubation, not receiving any corticosteroid or non-steroid painkillers and absence of respiratory diseases such as asthma or chronic lung disease. These patients were randomly assigned to three groups through permuted block randomization and underwent the treatment with nebulized Budesonide, intravenous dexamethasone and normal saline according to the group they were assigned to. Interventions included: Intervention group 1: receiving a dosage of 1mg in 4cc of nebulized budesonide every 12 hours (for 48 hours), each time for 20 minutes and 2 ml intravenous normal saline every 8 hours as well. Intervention group 2: receiving a dosage of 8 mg intravenous dexamethasone per 8 hours for 48 hours and receiving 4ml normal saline every 12 hours through nebulizer as well. Control group: receiving 2 ml intravenous normal saline per 8 hours as well 4 ml normal saline per 12 hours through nebulizer. Finally, pulse oximetry and cardiac signs were monitored in these subjects at the start of the study (zero hours) and 12, 24, 36 and 48 hours after intubation and parameters such as Oxygen saturation, Mean Arterial Pressure, Heart Rate, and Cuff Leak Rate were recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061734598N1**

Registration date: **2017-09-15, 1396/06/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-15, 1396/06/24

Registrant information

Name

Mehdi Heidari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 1605

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jam@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator.

Expected recruitment start date

2011-12-31, 1390/10/10

Expected recruitment end date

2012-12-31, 1391/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Nebulized Budesonide and Intravenous Dexamethasone on Tracheal Tube Cuff Leak in Intubated Patients Admitted to Intensive Care Unit

Public title

The Effects of Nebulized Budesonide and

Dexamethasone on Patients Using Tube for Ventilation.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the age range of 65-18 years; at least 48 hours of intubation; admission to intensive care unit and patient or his family's consent to participate in the study. Exclusion criteria: receiving corticosteroids; respiratory disease such as asthma or chronic lung disease; chronic consumption of NSAIDs.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **270**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Isfahan University of Medical Sciences.

Street address

Isfahan University of Medical Sciences, Hezar jerib St., Isfahan, Iran.

City

Isfahan

Postal code

81746-73461

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.MUI.REC.1395.3.291

Health conditions studied

1

Description of health condition studied

Head trauma.

ICD-10 code

S07.9

ICD-10 code description

Crushing injury of head, part unspecified

2

Description of health condition studied

Loss of Consciousness.

ICD-10 code

R40.2

ICD-10 code description

Coma, unspecified

3

Description of health condition studied

Surgery.

ICD-10 code

T88.9

ICD-10 code description

Complication of surgical and medical care, unspecified

4

Description of health condition studied

Poisoning

ICD-10 code

T50.4

ICD-10 code description

Drugs affecting uric acid metabolism

Primary outcomes

1

Description

Oxygen saturation.

Timepoint

At the beginning of the study (zero hour) and 12, 24, 36 and 48 hours after intubation.

Method of measurement

Pulse oximetry device.

2

Description

Mean Arterial Pressure.

Timepoint

At the beginning of the study (zero hour) and 12, 24, 36 and 48 hours after intubation.

Method of measurement

Cardiac monitoring.

3

Description

Heart Rate.

Timepoint

At the beginning of the study (zero hour) and 12, 24, 36 and 48 hours after intubation.

Method of measurement

Cardiac monitoring.

4

Description

Cuff Leak Rate

Timepoint

At the beginning of the study (zero hour) and 12, 24, 36 and 48 hours after intubation.

Method of measurement

(Average volume of exhaust flow at 3 breaths with low current volume - Current volume of the device)/Current volume of the device =CLR

Secondary outcomes

empty

Intervention groups

1

Description

Control group: receiving 2 ml intravenous normal saline per 8 hours as well 4 ml normal saline per 12 hours through nebulizer.

Category

Treatment - Other

2

Description

Intervention group 2: receiving a dosage of 8 mg intravenous dexamethasone per 8 hours for 48 hours and receiving 4ml normal saline every 12 hours through nebulizer as well.

Category

Treatment - Other

3

Description

Intervention group 1: receiving a dosage of 1mg in 4cc of nebulized budesonide every 12 hours (for 48 hours), each time for 20 minutes and 2 ml intravenous normal saline every 8 hours as well.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Intensive Care Unit in Alzahra hospital

Full name of responsible person

Dr. Saeed Abbasi

Street address

Anesthesiology department, University of Medical Sciences, Isfahan, Iran.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mehdi Nematbakhsh

Street address

Isfahan University of Medical Sciences, Isfahan, Iran.

City

Isfahan

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 of Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Abbas Emami nejad

Position

Resident in Anesthesia

Other areas of specialty/work

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Dr. Abbas Emami nejaad

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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