Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between Budesonide and saline use on the time of the weaning from Mechanical ventilation for patients in ICU

Protocol summary

Summary

Mechanical ventilatory support is a critical component in the management of patients with respiratory failure in intensive care units (ICU). Weaning from mechanical ventilation is paramount importance. The object of this study is to assess of the effect of inhalational Budesonide in time decreasing to weaning, in difficult weaning patients in ICU. In a randomized clinical trial, 120 patients in ICU were assigned to receive inhalatory Budesonide 0/5 mg/day or normal saline (control group), randomly. Intubated patients difficult to wean with duration of ICU stay less than 21 days, were included in the study. Patients with bronchiectasis, sepsis or Systemic Inflammatory Response Syndrome (SIRS) were excluded from the study. The variables of the respiratory system including pressure support and dynamic compliance and Interleukin 8 (IL-8) and Tumor necrosis factor alpha (TNF-a) in bronchoalveolar lavage for comparison in tow groups were measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030920592N5**
Registration date: **2016-05-08, 1395/02/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-08, 1395/02/19

Registrant information

Name

Seyed Mohammad Reza Hashemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2610 9944

Email address

iran.criticalcare@yahoo.com

Recruitment status

Recruitment complete

Funding source

none

Expected recruitment start date

2014-01-28, 1392/11/08

Expected recruitment end date

2016-01-28, 1394/11/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between Budesonide and saline use on the time of the weaning from Mechanical ventilation for patients in ICU

Public title

Comparison of Budesonide and saline on weaning from Mechanical ventilation

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria: intubated patients difficult to wean; duration of ICU stay less than 21 days. The exclusion criteria: patients with bronchiectasis, sepsis or Systemic Inflammatory Response Syndrome, pleural effusion, and Ventilator-Associated Pneumonia

Age

From **15 years** old to **80 years** old

Gender

Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
In this double blind study neither the patients, the experimenter were not aware of type of intervention.Randomized block design was used to random allocation of patients to two groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences, Yemen Street,Shahid Chamran Highway, Tehran, Iran
City
Tehran
Postal code
Approval date
2013-10-30, 1392/08/08
Ethics committee reference number
SBMU1.REC.1392.48

Health conditions studied

1

Description of health condition studied
weaning of mechanical ventilation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Number of days of mechanical ventilation
Timepoint
In start of the study and after 5 days
Method of measurement
observation

Secondary outcomes

empty

Intervention groups

1

Description
intervention:Budesonide This group received inhaler Budesonide 1 h before extubation and treatment continued up to 48 h after extubation. Patients underwent the therapy with budesonide at a dosage of 0/5 mg diluted in 4 cc of sterile water for 20 minutes.
Category
Treatment - Drugs

2

Description
control: Normal Saline Normal Saline was administered intra venous at a dosage of 0.15 mg/kg, one hour before extubation. After extubation, the administration of normal saline continued at the same dosage every 12 hour for 48 hour.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Seyed Mohammadreza Hashemian
Street address
Masih Daneshvari Hospital, Darabad, Niavaran Sq, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Mehdi Sadoughi, investigator
Street address
Shahid Beheshti University of Medical Sciences, Tabnak Street, Shahid Chamran Highway, Tehran, Iran
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, Shahid Beheshti 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
Masih Daneshvari Hospital
Full name of responsible person
Seyed Mohammadreza hashemian
Position
Associate professor
Other areas of specialty/work
Street address
Masih Daneshvari Hospital, Darabad, Niavaran Sq, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 2610 9512
Fax
Email
iran.criticalcare@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Masih Daneshvari Hospital
Full name of responsible person
Seyed Mohammad reza hashemian
Position
Associate professor
Other areas of specialty/work
Street address
Masih Daneshvari Hospital, Darabad, Niavaran Sq, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 2610 9512
Fax
Email
iran.criticalcare@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Masih Daneshvari Hospital
Full name of responsible person
seyed mohammad reza hashemian
Position
Associate Professor
Other areas of specialty/work
Street address
Masih Daneshvari Hospital, Darabad, Niavaran Sq, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 2610 9512
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Email
iran.criticalcare@yahoo.com
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