Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of weaning from mechanical ventilation as " Spontaneos breathing triales," with "Sincronised Intermident Mandatory Ventilation "

Protocol summary

Summary

The goal of this study will be compared Spontaneous breathing trials (SBT) method after extubation with Synchronized Intermittent Mandatory Ventilation (SIMV) during the weaning of ICU patients from mechanical ventilation. Inclusion criteria: age over 18 years; intubation for more than 48 hours; Weaning from mechanical ventilation based on doctor’s order Exclusion criteria: patient intolerance; occurring possible problems on physiological conditions of the patient; This is a clinical trial study which after selecting 44 samples based on convenience method and then randomly based on drawing method will allocate into two experimental & controlgroups. Data will be collection physiological status check list which before and after the weaning of the patient from mechanical ventilation will be filled. Exclusion criteria: the patient's intolerance; possible problems during the separation of the physiological condition of the patient; family dont wanting to this research will be continue on their patients, This Clinical triales study, 44 samples were select in such a way that the two groups were select (experimental & control) Data collection using physiological status of patients before and after the check list of weaning from mechanical ventilation.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015092821896N4**
Registration date: **2015-10-18, 1394/07/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-10-18, 1394/07/26

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of weaning from mechanical ventilation as " Spontaneos breathing triales," with "Sincronised Intermident Mandatory Ventilation "

Public title

Comparison of weaning from mechanical ventilation as " Spontaneos breathing triales ," with " Sincronised Intermident Mandatory Ventilation "

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: age over 18 years; intubation for more than 48 hours; Weaning from mechanical ventilation based on doctor’s order Exclusion criteria: patient intolerance; occurring possible problems on physiological conditions of the patient
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Data randomly divided into 2 groups and control.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University Of Medical Sciences
Street address
Arak, Sardasht,arak university of medical science,the college of nursing and midwifery
City
Arak
Postal code
Approval date
2015-09-23, 1394/07/01
Ethics committee reference number
IR.ARAKMU.REC.1394.165

Health conditions studied

1

Description of health condition studied
Improve breathing
ICD-10 code
Z51.8
ICD-10 code description
Other specified medical Care

Primary outcomes

1

Description
Improve breathing and oxygenation in patients after weaning from Ventilatorr
Timepoint
When the study and 3 months after the study
Method of measurement
check list

Secondary outcomes

1

Description
-
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
" Intervention group" : At 8 o'clock first the parameters of Pao2, o2sat, respiratory rate, breathing patterns, heart rate, systolic blood pressure, diastolic blood pressure, and level of consciousness will measured and checklist will filled. If weaning from the ventilatortakes place, periodically every 1 hour until 12 mid daily those parameters will be measured.In method of SBT changes in respiratory parameters of mechanical ventilator for patient will start with change (A/C) mode to continuous positive airway pressure (CPAP) gradually, then by using (T piece) patients will extubate from ventilator.
Category
Treatment - Other

2

Description
" Control Group" : The routine method of Synchronized intermittent mandatory ventilation will be used on the patients. First at 8 o’clock via check list of physiological indices the patient will be checked and, if he/she has order of weaning, the process will start using SIMV. In this method, every half hour 2 breath rate will reduced. If respiratory muscles weakness will occurred immediately the breath of the patient will return to previous pattern. Then after 24 hours the procedure on the patient will repeated.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin Didactic & Remedial Center
Full name of responsible person
Ms Hajian Leila
Street address
Amiralmomenin Hospita center,Sardasht,Arak,Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Arak University Of Medical Sciences
Full name of responsible person
Dr Rafii
Street address
Sardasht,Arak University Of Medical Science
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Arak
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 Arak 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
College Of Nursing & Midwifery
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Mahmoudi Mokhtar
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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