

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of weaning from mechanical ventilation as " Spontaneous breathing trials," with "Sincronised Intermident Mandatory Ventilation "

Protocol summary

2015-10-18, 1394/07/26

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 & control groups. 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 trials 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.

Registrant information

Name

Mokhtar Mahmoudi

Name of organization / entity

Iran University Of Medical Science

Country

Iran (Islamic Republic of)

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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

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

Scientific title

Comparison of weaning from mechanical ventilation as " Spontaneous breathing trials," with "Sincronised Intermident Mandatory Ventilation "

Public title

Comparison of weaning from mechanical ventilation as " Spontaneous breathing trials ," 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 Ventilator

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 ventilator takes 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

City

Arak

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

City

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

Full name of responsible person

Mahmoudi Mokhtar

Position

Msc in nursing

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