

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The comparison of two methods of ventilation (Bag mask ventilation vs Semi-open ventilation) on O2 saturation of patients undergoing Electro Convulsive Therapy (ECT)

Protocol summary

Summary

The aim of this single-blind randomized trial is to assess the effect of semi-open ventilation system on arterial oxygen saturation. In this study, 72 eligible patients who are scheduled for electroconvulsive therapy under general anesthesia are conducted to the study. The patients are divided into two groups (Control and Test) using random allocation. During anesthesia, the patients in the Test group are ventilated by semi-open system and the patients in the Control group are ventilated by Ambu-bag system. Arterial oxygen saturation (SpO₂) is recorded before and after preoxygenation as well as before convulsion as basic data. Arterial oxygen saturation is recorded one-minute interval after convulsion until recovery of spontaneous ventilation is adequate. Statistical analysis is done after collecting date.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504162832N2**

Registration date: **2015-05-16, 1394/02/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-16, 1394/02/26

Registrant information

Name

Mahmood Akhlaghi

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 3333 4691

Email address

akhlaghi@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research, Shahrekord university of Medical Sciences

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of two methods of ventilation (Bag mask ventilation vs Semi-open ventilation) on O₂ saturation of patients undergoing Electro Convulsive Therapy (ECT)

Public title

The comparison of two methods of ventilation during Electro Convulsive Therapy (ECT)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: candidates for ECT; age of 18-50 years; ASA 1 or 2 Exclusion criteria: patients with cardiovascular or respiratory diseases; ASA 3 or 4; patients with internal medicine diseases; lack of consent

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 72

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences, Kashani Street

City

Shahrekord

Postal code**Approval date**

2010-08-20, 1389/05/29

Ethics committee reference number

90-3-4

Health conditions studied**1****Description of health condition studied**

General Anesthesia during Electro Convulsive Therapy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Arterial Oxygen Saturation

Timepoint

Before ECT and 10 minutes thereafter

Method of measurement

Percent of arterial oxygen saturation using pulse

oximetry

Secondary outcomes

empty

Intervention groups**1****Description**

Using ventilation with Semi-open system in the Test group.

Category

Prevention

2**Description**

Using ventilation with Ambu-bag system in the Control group.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Psychiatry ward, Hajar hospital

Full name of responsible person

Mahmood Akhlaghi

Street address

Anesthesiology Department, Shahrekord University of Medical Sciences

City

Shahrekord

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahrekord University of Medical Sciences

Full name of responsible person

Dr. Mahmood Mobasheri

Street address

Deputy of Research, Shahrekord University of Medical Sciences, Kashani Street

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Shahrekord

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahrekord 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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Shahrekord University of Medical Sciences

Full name of responsible person

Mahmood Akhlaghi

Position

Associate Professor of Anesthesiology Department,
Academic Staff

Other areas of specialty/work**Street address**

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Anesthesiologist

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City**Person responsible for updating data****Contact****Name of organization / entity**

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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