

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Sep 2026

Evaluating the Impact of a Scoring System and Anesthesia Guide on Early Diagnosis and Intervention in the Post Anesthesia Care Unit

Protocol summary

Study aim

Determining the effect of a scoring system and anesthesia expert guidance on early diagnosis and intervention in the post-anesthesia care unit

Design

A clinical trial with a control group with parallel groups, randomized, on 50 patients

Settings and conduct

The present study is a randomized controlled trial in PACU of one of Ahvaz teaching hospitals. The statistical population of this study consists of all patients who will undergo abdominal and thoracic surgery and then be monitored in PACU. Random division of patients is done in the preoperative period. To achieve an equal distribution of patients in the groups, randomization will be performed after determining the total number of patients undergoing surgery on the same day. To do this, patients are asked to pull out a sealed envelope with the study or control group written on it.

Participants/Inclusion and exclusion criteria

Including age over 18, volunteering to participate in this study, undergoing general anesthesia for abdominal or chest surgery, no history of general anesthesia in the past 6 months, and no intraoperative complications

Intervention groups

All patients are scored according to EWSS during the PACU course. Patients in the control group do not receive any intervention as directed by the anesthesiologist's guide, even if they have a high score. Patients in the study group receive the necessary interventions as indicated in the anesthesiologist's guide.

Main outcome variables

Patients' EWSS score; Length of stay in the PACU; Complications in the PACU; Complication treatment time; Treatments performed

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210222050463N1**

Registration date: **2021-03-06, 1399/12/16**

Registration timing: **prospective**

Last update: **2021-03-06, 1399/12/16**

Update count: **0**

Registration date

2021-03-06, 1399/12/16

Registrant information

Name

Noushin Sarvi Sarmeidani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3390 6395

Email address

sarvi.n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-20, 1399/12/30

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Impact of a Scoring System and Anesthesia Guide on Early Diagnosis and Intervention in the Post Anesthesia Care Unit

Public title

A guidance system in the post-anesthesia care unit

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years Volunteer to participate in this research Under general anesthesia for abdominal or chest surgery

Exclusion criteria:

Have a history of general anesthesia in the last 6 months Having a threatening surgical complication during the operation

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization of the patients was performed during the preoperative period. The patients were requested to draw one of the two sealed envelopes; one denoting the study group and the other denoting the control group. To achieve equal distribution of the patients to the groups, Simple individual randomization was performed after the total number of patients who would undergo the operation at the same day was determined. If the total number of patients was 6 on a certain day and 3 of them drew the study group envelope, the rest of the patients were just allocated to the control group without drawing envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address

Ahwaz Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6143975617

Approval date

2021-02-05, 1399/11/17

Ethics committee reference number

IR.AJUMS.REC.1399.891

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

Cardiopulmonary complications

ICD-10 code

R00-R09

ICD-10 code description

Symptoms and signs involving the circulatory and respiratory systems

Primary outcomes**1****Description**

Early warning scoring system score

Timepoint

Data for this period are collected after the patient is admitted to the PACU

Method of measurement

1. Calculating the EWSS score of patients In this study, an anesthesiologist's guide is used, this guide has been prepared to achieve the standard of care by referring to published articles.

2**Description**

length of stay in PACU

Timepoint

Data for this period are collected after the patient is admitted to the PACU

Method of measurement

Record patient results: length of stay in PACU

3**Description**

Complications created in the PACU

Timepoint

Data for this period are collected after the patient is admitted to the PACU

Method of measurement

Record patient results: Complications of PACU (respiratory, pain, hypotension, nausea and vomiting, etc.)

4**Description**

Complications treatment time

Timepoint
Data for this period are collected after the patient is admitted to the PACU

Method of measurement
Record patient results: Treatment time of patients' complications in recovery in minutes

5

Description
Treatments performed

Timepoint
Data for this period are collected after the patient is admitted to the PACU

Method of measurement
Recording patient results: treatments performed for the patient by anesthesiologist (respiratory intervention, fluid therapy, positioning, additional tests, etc.)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the study group receive the necessary interventions as indicated in the anesthesiologist's guide. If the score is $EWSS \leq 4$, the patient is monitored every 10 minutes. If the patient's EWSS score is 5, the patient is monitored every 5 minutes. If the patient's score does not change, monitoring is continued every 5 minutes. However, if the patient's score drops to ≤ 4 , monitoring is performed every 10 minutes. If the score increases, the follow-up will continue for 5 minutes and the emergency team will be called to evaluate the patient.

Category
Early detection

2

Description
Control group: All patients are scored according to EWSS during the PACU period. Patients in the control group do not receive any intervention as directed by the anesthesiologist, even if they have a high score.

Category
Early detection

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Teaching Hospitals
Full name of responsible person
Ali Khalafi

Street address
Ahvaz Jundishapur University
City
Ahvaz
Province
Khouzestan
Postal code
6143975617
Phone
+98 61 3390 6395
Email
nooshinsarvi9192@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Ali Biranvand
Street address
Ahvaz University of Medical Sciences
City
Ahvaz
Province
Khouzestan
Postal code
6143975617
Phone
+98 61 3390 6395
Email
nooshinsarvi9192@gmail.com

Grant name
Research committee of Ahvaz Jundishapur university of medical sciences

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

Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
100

Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty

Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Noushin Sarvi Sarmeidani

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

Street address

Ahwaz University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6143975617

Phone

+98 61 3390 6395

Email

nooshinsarvi9192@gmail.com

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

Ahvaz University of Medical Sciences

Full name of responsible person

Noushin Sarvi Sarmeidani

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

Street address

Ahwaz University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6143975617

Phone

+98 61 3390 6395

Email

nooshinsarvi9192@gmail.com

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

Ahvaz University of Medical Sciences

Full name of responsible person

Noushin Sarvi Sarmeidani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

Street address

Jundishapur Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6143975617

Phone

+98 61 3390 6395

Fax**Email**

sarvi.n@ajums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available