

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### Study of the effect of Nursing Interventions based on Bern's tool on the success rate of Weaning

#### Protocol summary

##### Study aim

Determining of the effect of nursing interventions based on Bern's tool on the success rate of Weaning in the intensive care unit

##### Design

This research is a clinical trial with a sample size of 70 people. The method of assigning intervention to patients was randomized and random blocked blocks with block size 4 (using the table for random permutations). The randomization list is provided by a statistic specialist. The intervention used in this study is based on a randomized list by a person outside the study who is not aware of the research objectives and will be handled according to the corresponding codes within the sealed envelopes. In this way, the samples will be divided into two groups of intervention and control.

##### Settings and conduct

ICU Department of Ahvaz Golestan Hospital

##### Participants/Inclusion and exclusion criteria

Age of 18-65 Failure to develop Neuromuscular diseases  
Do not receive Neuromuscular blockers Exclusion  
Criteria: Brain death patients

##### Intervention groups

The intervention group consists of all patients aged 18-65 years old admitted to the intensive care unit and connected to a mechanical ventilation device, which will be weaning from the machine according to the criteria of the Bern list. weaning of the control group is performed according to the routine procedure.

##### Main outcome variables

Successful and unsuccessful weaning and Burn number  
Duration of mechanical ventilation The number of re-intubation The index RSBI Length of stay in ICU

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181113041632N1**

Registration date: **2018-12-26, 1397/10/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-12-26, 1397/10/05**

Update count: **0**

##### Registration date

2018-12-26, 1397/10/05

##### Registrant information

###### Name

Maryam Sepahyar

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3443 0804

###### Email address

sepahyar.m@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-11, 1397/08/20

##### Expected recruitment end date

2019-02-09, 1397/11/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of the effect of Nursing Interventions based on Bern's tool on the success rate of Weaning

##### Public title

The effect of Nursing Interventions based on Bern's tool

on the success rate of Weaning

IR.AJUMS.REC.1397.599

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age of 18-65 Years Failure to develop Neuromuscular diseases Do not receive Neuromuscular blockers

### Exclusion criteria:

Brain death Patients

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The method of assigning intervention to patients was randomized and random blocked blocks with block size 4 (using the table for random permutations). A randomized list is provided by a statistician. The interrogation used in this study is based on a randomized list by a person outside the study who is not aware of the research objectives and will be conducted according to the different codes in the sealed envelopes.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Other

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

##### Street address

No. 104, Rezvan2 Ave, Payam Town

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6138815339

#### Approval date

2018-11-10, 1397/08/19

#### Ethics committee reference number

## Health conditions studied

### 1

#### Description of health condition studied

Traumatic patients connected to a mechanical ventilation device

#### ICD-10 code

S06.3

#### ICD-10 code description

Focal traumatic brain injury

### 2

#### Description of health condition studied

Traumatic patients connected to a mechanical ventilation device

#### ICD-10 code

S06.4

#### ICD-10 code description

Epidural hemorrhage

### 3

#### Description of health condition studied

Traumatic patients connected to a mechanical ventilation device

#### ICD-10 code

S06.5

#### ICD-10 code description

Traumatic subdural hemorrhage

### 4

#### Description of health condition studied

Traumatic patients connected to a mechanical ventilation device

#### ICD-10 code

S06.6

#### ICD-10 code description

Traumatic subarachnoid hemorrhage

## Primary outcomes

### 1

#### Description

Successful and unsuccessful weaning

#### Timepoint

From weaning to 48 hours after it

#### Method of measurement

Registration in vital-laboratory variables questionnaire

## Secondary outcomes

### 1

#### Description

Duration of mechanical ventilation connection

#### Timepoint

The number of days a patient connected to a ventilator

**Method of measurement**

Record in vital-laboratory questionnaire

**2**

**Description**

Length of admission to the intensive care unit

**Timepoint**

From the time of admission to the intensive care unit until the discharge from this department

**Method of measurement**

Demographic information questionnaire

**3**

**Description**

The number of re-intubation

**Timepoint**

From the beginning of the patient's connection to the ventilator until the patient's discharge from the department

**Method of measurement**

Vital Laboratory Information Questionnaire

**4**

**Description**

The RSBI index is the day before and after the weaning

**Timepoint**

The day before weaning and at the time of weaning

**Method of measurement**

Vital Laboratory Information Questionnaire

**Intervention groups**

**1**

**Description**

Nurses will plan and conduct nursing care for patients undergoing mechanical ventilation in the intervention group, according to Bern's checklist criteria. The researcher will evaluate the patients on a daily basis according to the checklist, and will complete the checklist for the intervention group, and will assess the readiness of the patient's weaning. If the optimal score (17 and above) is obtained, the process of weaning begins. In the absence of a desirable score, nursing interventions will focus more on the main problem that is identified in Bern during the day.

**Category**

Treatment - Other

**2**

**Description**

Control group: In the control group according to routine medical and weaning of patients with the use of certain criteria and will be done experimentally. The routine weaning method is such that the patient is alert, has a good cough and swallowing reflex, has no respiratory ventilation, and respiratory rate is not more than 35.

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Golestan hospital

**Full name of responsible person**

Shahram Baraz

**Street address**

Golestan, Farvardin Ave., Golestan hospital

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135733118

**Phone**

+98 61 3374 3001

**Fax**

+98 61 3374 3030

**Email**

golestanhospital@ajums.ac.ir

**Web page address**

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Shahram Baraz

**Street address**

Jundishapur University of Medical Sciences, Golestan Blvd

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715794

**Phone**

+98 61 3333 0250

**Fax**

**Email**

info@ajums.ac.ir

**Web page address**

ttp://ajums.ac.ir

**Grant name**

**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**

Maryam Sepahyar

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No.104, Rezvan2 Ave, Payam Town

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6138815339

**Phone**

+98 61 3443 0804

**Fax**

**Email**

sepahyar.m@ajums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Maryam Sepahyar

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No.104, Rezvan2 Ave, Payam Town

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6138815339

**Phone**

+98 61 3443 0804

**Fax**

**Email**

sepahyar.m@ajums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Maryam Sepahyar

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No.104, Rezvan2 Ave, Payam Town

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6138815339

**Phone**

+98 61 3443 0804

**Fax**

**Email**

sepahyar.m@ajums.ac.ir

**Sharing plan**

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Information on age, sex, history of underlying illness, history of smoking and drug use, and duration of admission

**When the data will become available and for how long**

6 months after the publication of results

**To whom data/document is available**

Researchers of academic and academic institutions

**Under which criteria data/document could be used**

Use results

**From where data/document is obtainable**

maryamsepahyar@yahoo.com 0098 61 9166003501

**What processes are involved for a request to access data/document**

One to two weeks after the call

**Comments**

