

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The effect of implementing pain control instructions on sedation and duration of mechanical ventilation in patients admitted to the intensive care unit of Hakim Jorjani Hospital in 2020

#### Protocol summary

##### Study aim

Determining the effect of implementing pain control instructions on sedation and duration of mechanical ventilation in patients admitted to the intensive care unit of Hakim Jorjani Hospital in 2020

##### Design

Clinical trial with control group, With parallel, Non-blind, Randomized, Groups on 40 patients

##### Settings and conduct

In the intensive care unit of Hakim Jorjani Hospital in Gorgan. Patients who are on Constant positive pressure or Spontaneous mode are evaluated according to pain control guidelines. The patient's sedation is interrupted, Fentanyl (1 micrograms per kilogram per hour) infused as needed. After 4 hours, the patient is evaluated according to a Burn checklist. When a score above 17 is obtained, The separation is performed as follows: Injection of a dose of intravenous dexamethasone, Application of one hour of oxygen 6 to 7 liters per minute on the T-piece, If tolerated if the endotracheal tube, after oxygenated, The tube is removed and if Having a truck, the administration of oxygen is interrupted by a T-piece. The patient is constantly monitored to connect to the ventilator if needed and to be among the unsuccessful cases; If tolerated, It will be one of the successful cases.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: having a endotracheal tube or tracheostomy, need for a ventilator, score higher than 3 Richmond scale, score 5 to 13 of the Glasgow scale. Exclusion Criteria: Having kidney disease, Allergy to Morphine and Fentanyl

##### Intervention groups

Intervention group: Pain control instructions, pain behavioral scale and Richmond relaxation scale are performed and if sedation is needed according to these tools. according to the Bern checklist, separation from the

ventilator is done according to the protocol. Control group: No additional drugs or placebo are administered

##### Main outcome variables

Pain control; Sedation; Duration of mechanical ventilation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210906052394N1**

Registration date: **2021-10-18, 1400/07/26**

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

Last update: **2021-10-18, 1400/07/26**

Update count: **0**

##### Registration date

2021-10-18, 1400/07/26

##### Registrant information

##### Name

Maryam Zarei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 4332 3916

##### Email address

maryam.zareia1369@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-11, 1400/06/20

##### Expected recruitment end date

2021-10-22, 1400/07/30

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty  
**Scientific title**  
The effect of implementing pain control instructions on sedation and duration of mechanical ventilation in patients admitted to the intensive care unit of Hakim Jorjani Hospital in 2020

**Public title**  
Implementation of pain control instructions on sedation and duration of mechanical ventilation in patients admitted to the intensive care unit

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Having a endotracheal tube or tracheostomy tube Need for mechanical ventilation Inability to communicate verbally Insensitivity to Morphine and Fentanyl No kidney disease Having a systolic blood pressure greater than 100 mm Hg A score above 3 on the Richmond scale A score between 5 Up to 13 on the Glasgow scale

**Exclusion criteria:**

Allergy to Morphine and Fentanyl Having kidney disease Score below 3 on the Richmond Scale Having a systolic blood pressure of less than 100 mm Hg

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 20

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**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

Islamic Azad University, Chalous Branch  
**Street address**  
Shahid Amini alley ,60 metri Ave,Emam Ali Blvd  
**City**  
Marvdasht  
**Province**  
Fars  
**Postal code**  
7371753519

**Approval date**

2020-09-08, 1399/06/18

**Ethics committee reference number**

IR.IAU.CHALUS.REC.1399.019

**Health conditions studied**

1

**Description of health condition studied**

Pain Control

**ICD-10 code**

**ICD-10 code description**

2

**Description of health condition studied**

Sedation

**ICD-10 code**

**ICD-10 code description**

3

**Description of health condition studied**

Mechanical Ventilation

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

Pain control

**Timepoint**

Consecutively every 4 hours after starting the study

**Method of measurement**

Behavioral tools for measuring pain(BPS)

2

**Description**

Sedation

**Timepoint**

Consecutively every 4 hours after starting the study

**Method of measurement**

Richmond agitation sedation acale

3

**Description**

Duration of mechanical ventilation

**Timepoint**

Consecutively every 4 hours after starting the study  
**Method of measurement**  
BURNS' WEAN ASSESSMENT PROGRAM (BWAP)

+98 71 4332 2047  
**Email**  
Maryam.zareia1369@gmail.com

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The patient is evaluated every 4 hours according to the Pain Control Instruction. If the patient needs pain relief (pain assessment with Pain Behavioral Scale), morphine 1 to 5 mg is used intravenously and Repeat every 10 minutes if needed. Maximum to 10 milligram per kilogram per hour is used. If the patient is not relieved with this amount of drug, it is evaluated using the Richmond sedation criterion and if necessary, 1 to 4 milligram of midazolam is injected intravenously. Repeat every 15 minutes if needed. Maximum to 10 milligram per hour can be used. At the threshold of separation from the mechanical ventilation device, the patient's sedation is discontinued and if necessary, fentanyl is infused at a dose of 1 micrograms per kilogram per hour. 4 hours after separation from the mechanical ventilator, using the Bern checklist, if a patient scores above 17, we use a single dose of intravenous dexamethasone (0.1 milligram per kilogram).

#### Category

Behavior

### 2

#### Description

Control group: "The control group continues to receive sedations as directed by the physician and does not receive any additional medications or placebos.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hakim Jorjani Hospital, Gorgan

##### Full name of responsible person

Maryam Zarei

##### Street address

Shahid Amini alley, 60 Metri Ave,Emam Ali Blvd

##### City

Marvdasht

##### Province

Fars

##### Postal code

7371753519

##### Phone

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Scientific Association of Islamic Azad University,  
Aliabad Katoul Branch

##### Full name of responsible person

Maryam Zarei

##### Street address

Shahid Amini alley, 60 Metri Ave,Emam Ali Blvd

##### City

Marvdasht

##### Province

Fars

##### Postal code

7371753519

##### Phone

+98 71 4332 2047

##### Email

Maryam.zareia1369@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

Islamic Azad University, Aliabad Katoul Branch

#### Proportion provided by this source

100

#### Public or private sector

Private

#### 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

Islamic Azad University

##### Full name of responsible person

Maryam Zarei

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Anesthesiology

##### Street address

Shahid Amini alley,60 Metri Ave,Emam Ali Blve

##### City

Marvdasht

**Province**

Fars

**Postal code**

7371753519

**Phone**

+98 71 4332 2047

**Email**

Maryam.zareia1369@gmail.com

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

Islamic Azad University

**Full name of responsible person**

Maryam Zarei

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Shahid Amini alley,60 Metri Ave,Emam Ali Blvd

**City**

Marvdasht

**Province**

Fars

**Postal code**

7371753519

**Phone**

+98 71 4332 2047

**Email**

Maryam.zareia1369@gmail.com

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

Islamic Azad University

**Full name of responsible person**

Maryam Zarei

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Shahid Amini alley,60 Metri Ave,Emam Ali Blvd

**City**

Marvdasht

**Province**

Fars

**Postal code**

7371753519

**Phone**

+98 71 4332 2047

**Email**

Maryam.zareia1369@gmail.com

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information.

**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