

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison effect of two implemented sedation methods (Scale & protocol) by nurses on some consequences of mechanical ventilation in intensive care patients

#### Protocol summary

##### Summary

This study will implement with aim survey effect of two sedation method (Protocol and Scale) on some consequences of mechanical ventilation in patients who are under mechanical ventilation in ICU ward. inclusion criteria: age above18y and under 65y; under mechanical ventilation with Positive pressure; attachment to mechanical ventilation more than 48h; need to sedative drugs in treatment plan. exclusion criteria: Tracheostomy; weaning before 24h; using neuromuscular blocker drugs; pneumonia before 48h of atctment to mechanical ventilation. population is including all of patients under mechanical ventilation in Alzahra's Hospital in Isfahan, Iran and sample size is 25 patients of them in each group. intervention is including use of Richmond Scale and researchers made Protocol on some of the consequences of mechanical ventilation such as pneumonia, mechanical ventilation duration, ventilator mode and etc.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201201098665N1**

Registration date: **2012-07-04, 1391/04/14**

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

Last update:

Update count: **0**

##### Registration date

2012-07-04, 1391/04/14

##### Registrant information

##### Name

Hassan Babamohamadi

##### Name of organization / entity

Semnan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3365 4190

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Research deputy of Semnan University of Medical Sciences

##### Expected recruitment start date

2012-06-21, 1391/04/01

##### Expected recruitment end date

2013-04-20, 1392/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison effect of two implemented sedation methods (Scale & protocol) by nurses on some consequences of mechanical ventilation in intensive care patients

##### Public title

Comparison effect of two implemented sedation methods (Scale & protocol) by nurses on some consequences of mechanical ventilation in intensive care patients

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

inclusion criteria: age above18y and under 65y; under mechanical ventilation with Positive pressure; attachment to mechanical ventilation more than 48h;

need to sedative drugs in treatment plan. exclusion criteria: Tracheostomy; weaning before 24h; using neuromuscular blocker drugs; after CPR; severe hearing loss; peripheral nervous system disorders; addiction; pneumonia before 48h of attachment to mechanical ventilation.

#### **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: **25**

#### **Randomization (investigator's opinion)**

Randomized

#### **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**

Semnan University of Medical Sciences

###### **Street address**

Semnan- Basidj Bolv- Central deputy of Semnan University of Medical Sciences- Research and Technology deputy

###### **City**

Semnan

###### **Postal code**

##### **Approval date**

2012-06-19, 1391/03/30

##### **Ethics committee reference number**

91/186190

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

pneumonia due to mechanical ventilation

##### **ICD-10 code**

j18

##### **ICD-10 code description**

Pneumonia, organism unspecified

#### **2**

##### **Description of health condition studied**

mechanical ventilation duration

##### **ICD-10 code**

j70.9

##### **ICD-10 code description**

Respiratory conditions due to unspecified external agent

#### **3**

##### **Description of health condition studied**

intra tracheal tube duration

##### **ICD-10 code**

y65.8

##### **ICD-10 code description**

Other specified misadventures during surgical and medical care

#### **4**

##### **Description of health condition studied**

time each of mechanical ventilation mode

##### **ICD-10 code**

z51.8

##### **ICD-10 code description**

Other specified medical care

### **Primary outcomes**

#### **1**

##### **Description**

clinical pneumonia due to mechanical ventilation

##### **Timepoint**

first and fourth day of admission

##### **Method of measurement**

physician diagnosis

### **Secondary outcomes**

#### **1**

##### **Description**

mechanical ventilation duration

##### **Timepoint**

hour

##### **Method of measurement**

from attachment to ventilator until weaning time

#### **2**

##### **Description**

hospitalization time in ICU

##### **Timepoint**

hour

##### **Method of measurement**

from admission in ICU until discharge time

#### **3**

##### **Description**

intra tracheal tube duration

**Timepoint**

hour

**Method of measurement**

from insertion tracheal tube until exiting

**4****Description**

mechanical ventilation modes

**Timepoint**

hour

**Method of measurement**

including Spont, SIMV, Bilevel

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

after finishing control group sampling, randomly in one section of ICU ward of Alzahra Hospital of Isfahan implement scale and in another part protocol. it is noticeable that selection of patients are based on empty bed not another factors. for elimination of effect of scale use for sedation preparation, scale group is considered. Nursing in scale group based on physician order inject sedation drugs similar to routine group but scale is available for them to use. In this group, sedation score of each patients measured by Richmond scale every 3 hours and then based on score, and physician order, nurse inject sedation drug. Researcher educate Richmond scale to nurses of wards to nurses inject sedation drugs based on scale. Also scale is attaching to wall of patients rooms for observation. Richmond scores of patients document by nurses every 3h. Allocation of patients in this group is randomly and based on inclusion criteria. in this group similar to control group physician order is base for drug prescription and followup is continued till attachment to ventilator or having endotracheal tube, and if done tracheostomy, followup terminate.

**Category**

Treatment - Drugs

**2****Description**

at first for determination of routine method effect on outcomes of mechanical ventilation, patients who have inclusion criteria are selected as samples and is done parameters. at current ways that is done for sadation of patients is including prescription of sedation drugs according to type, dosage, and injection via PRN method as physician order. in routine method, we use of fentanyl and morphine and midazolam via blous and PRN. these drugs is used without any scales and evaluation. nurses in this method have not any scheduled program for drug injection and decision making are based on intuition. followup duration for patients in this group is untill having endotracheal tube and attachment to ventilator. but if patient undergo tracheostomy followup terminate. drugs dosage for this group is based on physician order

and prescription by nurses.

**Category**

Treatment - Drugs

**3****Description**

In protocol group, at first agitation score of each patient measured by nurse, and if Richmond score of patient was more than zero, ventilators and other devices are assessed by nurse, and after correction of changeable causes (position ...), environment improvement, giving verbal confidence to patient, Midazolam and Fentanyl are inject. Injection of these drugs is bolus at first and based on calculated dosage for weight and time duration for each drugs in protocol that continue till obtaining relaxation namely Richmond score between 0 to -1. Then continuous infusion of drug based on patient's weight is started. Thereafter control of patient's sedation level is evaluated by nurse at q3h, and based on obtained score, continue drug dose with increase, decrease or unchanged. Goal is obtaining Richmond score between 0 to -1. If necessary to decrease or increase of drug dosage, it is done by increasing or decreasing 25% to primary dosage of drug by nurses (as infusion). Richmond scores are document q3h by nurses. Protocol was designed based on research results from 2005 to current that is according to sedation level evaluation by assessment tools with sedation prescription for achieving to optimal level of sedation that is leading to improved clinical outcomes and improved quality of treatment with sedation. This protocol is confirmed by ward physician. Education of protocol to ward nursed is done by researcher. Also protocol is attached to wall of patient's rooms for observation. Richmond scores for each patient are documented by nurses. Allocation of samples to each group is based on inclusion criteria and randomly. Drugs is including: 1) midazolam Bolus 0.05 mg/kg q5m untill richmond score 0 to -1 and after continous infusion of midazolam 0.03 mg/kg/hr. 2) Fentanyl bolus 1/5 microgram/kg q10m till richmond score 0 to -1 and after continous infusion of fentanyl 0.7 microgram/kg/hr. follow up duration is similar to routine and scale group till attachment to ventilator and having endotracheal tube. and if done tracheostomy for patient followup is terminate.

**Category**

Treatment - Drugs

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

Alzahra's Isfahan Hospital

**Full name of responsible person**

Mr Abasi Dorche, Saeed

**Street address**

Alzahra's Isfahan Hospital, ICU ward

**City**

Isfahan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Dr Ghorbani, Raheb

**Street address**

Semnan, Basidj Bolv, Central complex of Semnan  
University Of Medical Sciences

**City**

Semnan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Semnan 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**

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**Full name of responsible person**

Babamohamadi, Hassan

**Position**

Faulty member

**Other areas of specialty/work**

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## Person responsible for updating data

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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*