

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### The effects of nursing interventions on prevention of delirium in patients admitted to intensive care unit

#### Protocol summary

##### Study aim

Determining the effect of nursing care on delirium prevention in patients admitted to intensive care units

##### Design

This study is a randomized controlled clinical trial that will be done on 60 patients.

##### Settings and conduct

The aim of this study is to evaluate the effect of nursing care on Delirium prevention in patients admitted to the intensive care unit of Shahid Beheshti Hospital in Hamadan. In the intervention group, educational interventions for the prevention of delirium will be lectures and booklets for nurses. Also, the posters for training on prevention of delirium and its evaluation in the department will be installed. There is no action in the control group, and ICU's usual care will be taken in the past.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years, GCS score higher than 12 Exclusion criteria: Having drug addiction, Having chronic underlying disease

##### Intervention groups

In the intervention group, educational interventions for the prevention of delirium will be delivered as lectures and booklets for nurses. Also, the posters for training on prevention of delirium and its evaluation in the unit will be installed. There is no action in the control group, and ICU's usual care will be taken in the past.

##### Main outcome variables

Delirium

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160110025929N11**

Registration date: **2018-04-13, 1397/01/24**

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

Last update: **2018-04-13, 1397/01/24**

Update count: **0**

##### Registration date

2018-04-13, 1397/01/24

##### Registrant information

###### Name

Mehdi Molavi Vardanjani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3422 5056

###### Email address

m.molavi@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-21, 1397/01/01

##### Expected recruitment end date

2019-03-21, 1398/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of nursing interventions on prevention of delirium in patients admitted to intensive care unit

##### Public title

effects of nursing interventions on prevention of delirium

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Age over 18 years Satisfaction to participate in the study

GCS score higher than 12

**Exclusion criteria:**

Having Drug Addiction Having chronic underlying disease

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomly, 60 patients are selected. Then, using simple randomization method, they will be divided equally in to two groups of intervention and control.

**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 Hamadan University of Medical Sciences

**Street address**

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

**City**

Hamedan

**Province**

Hamadan

**Postal code**

38698-65178

**Approval date**

2017-11-28, 1396/09/07

**Ethics committee reference number**

IR.UMSHA.REC.1396.587

## Health conditions studied

### 1

**Description of health condition studied**

Delirium

**ICD-10 code**

F05

**ICD-10 code description**

Delirium due to known physiological condition

## Primary outcomes

### 1

**Description**

Delirium

**Timepoint**

Before and after intervention

**Method of measurement**

CAM-ICU Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: In the intervention group, nursing care for the prevention of delirium, which consists of three components, professional, environmental and related to the patient, will be carried out. The components of the professional component include training the personnel in relation to the definition and causes of the delirium ICU, the method of examining and diagnosis of delirium, and how to deal with a patient with delirium and ways to prevent delirium in ICU patients, first training in a two-hour session The lectures are provided for nurses and then the materials are provided in the form of a booklet. Also, the poster for the training of Delirium Prevention and Delirium Step-by-Step Assessment and Detection will be also provided. In the area of environmental interventions, such as setting the clock and the patient's view of the calendar, encouraging the patient to increase mobility, listening to radio and music, using proper day and night lighting, putting glasses and hearing aids at the patient's disposal, and Encouraging staff to engage more with the patient to inform the patient about time, place and recent events.

**Category**

Prevention

### 2

**Description**

Control group: In the control group, ICU routine care will be taken.

**Category**

Prevention

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Beheshti  
**Full name of responsible person**  
Reza Borzou  
**Street address**  
Beheshti St, Beheshti hospital, Hamadan  
**City**  
Hamedan  
**Province**  
Hamadan  
**Postal code**  
38698-65178  
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+98 81 3838 0535  
**Email**  
borzou@umsha.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Saeed Bashirian  
**Street address**  
Shahid Fahmideh St., University of Medical Sciences,  
Hamadan  
**City**  
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s-bashirian@umsha.ac.i

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Hamedan 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**  
Hamedan University of Medical Sciences

#### Full name of responsible person

Reza Borzou

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nursery

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#### Email

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## Person responsible for scientific inquiries

#### Contact

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Sepideh Radfar

#### Position

Student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Nursery

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## Person responsible for updating data

#### Contact

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Sepideh Radfar

#### Position

Student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Nursery

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**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