

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The effect of programmed tactile and auditory stimulations on consciousness level and cardiopulmonary parameters in patients with decreased consciousness level admitted in intensive care units.

#### Protocol summary

##### Summary

This study was conducted to determine effect of sensory stimulation on consciousness level and cardiopulmonary parameters of critical care patients. Inclusion criteria: patients from eighteen to sixty years old; admitted to ICU greater than 24 hours; consciousness level between 4 to 12 base on FOUR scale; presence of hemodynamic and electrolytes stability according to doctor idea. Exclusion criteria: malignancy and cardiopulmonary disease according to doctor idea; discharge from the ICU before fourth day and surgery after admitted. Participants were 50 patient hospitalized in intensive care unit that selected using convenience sampling and divided in 2 groups control and intervention. First, patient's consciousness level and cardiopulmonary parameters (systolic blood pressure, diastolic blood pressure, mean arterial blood pressure, respiratory rate and arterial blood oxygen saturation) were measured and recorded before intervention. In intervention group, the patient family after wearing gown and Slippers, washing hands and training about the correct procedure entered to ward and touched the patient and talked with him for 15 minute under the supervision of researcher, then left the ward for 2 hours, after that the intervention repeated in the same procedure. Consciousness level and cardiopulmonary parameters were recorded 30 minutes after intervention. In controls group simultaneously without any intervention consciousness level and cardiopulmonary parameters were recorded in 16 and 19 o clock.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014053117915N1**  
Registration date: **2014-07-12, 1393/04/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-07-12, 1393/04/21

##### Registrant information

###### Name

mehdi sahebi

###### Name of organization / entity

Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3838 0439

###### Email address

m.sahebi@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Hamadan University of Medical Sciences

##### Expected recruitment start date

2014-03-06, 1392/12/15

##### Expected recruitment end date

2014-06-22, 1393/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of programmed tactile and auditory stimulations on consciousness level and cardiopulmonary parameters in patients with decreased consciousness

level admitted in intensive care units.

### Public title

The effect of family communication and touch on unconscious patient

### Purpose

Supportive

### Inclusion/Exclusion criteria

Inclusion criteria: patient from eighteen to sixty years old; admitted to ICU greater than 24 hours; consciousness level base on FOUR scale between 4 to 12; presence of hemodynamic and electrolytes stability according to doctor idea; pass at least 6 hours from the time of opioid or sedative drugs injection. Exclusion criteria: malignancy and cardiopulmonary disease according to doctor idea; discharge from the ICU before fourth day and surgery after admitted.

### 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: **50**

### 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

Ethical Human Subject Review Board of Hamadan  
University of Medical Sciences

##### Street address

University of Medical Sciences, Shaheed Fahmideh  
Ave

##### City

Hamadan

##### Postal code

#### Approval date

2014-03-02, 1392/12/11

#### Ethics committee reference number

/16/35/9/4193/P/D

## Health conditions studied

### 1

#### Description of health condition studied

decreased level of consciousness

#### ICD-10 code

R40.2

#### ICD-10 code description

Coma, unspecified

## Primary outcomes

### 1

#### Description

level of consciousness

#### Timepoint

Before and 30 minutes after intervention

#### Method of measurement

FOUR scale

### 2

#### Description

Systolic blood pressure

#### Timepoint

Before and 30 minutes after intervention

#### Method of measurement

Connected to patient hemodynamic monitoring

### 3

#### Description

Diastolic blood pressure

#### Timepoint

Before and 30 minutes after intervention

#### Method of measurement

Connected to patient hemodynamic monitoring

### 4

#### Description

Mean arterial blood pressure

#### Timepoint

Before and 30 minutes after intervention

#### Method of measurement

Connected to patient hemodynamic monitoring

### 5

#### Description

Respiratory rate

#### Timepoint

Before and 30 minutes after intervention

#### Method of measurement

Connected to patient hemodynamic monitoring

### 6

#### Description

Oxygen saturation

#### Timepoint

Before and 30 minutes after intervention

**Method of measurement**

Connected to patient hemodynamic monitoring

**7**

**Description**

Heart rate

**Timepoint**

Before and 30 minutes after intervention

**Method of measurement**

Connected to patient hemodynamic monitoring

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

This intervention is performed in three 5 minute section twice on day between 16-16:15 and 18-18:15 hours for four day in the afternoon. The families in the intervention group after wearing gown and Slippers and washing hands and rubbing them with antibacterial jel enter the ward and sit on the chair near the bed, call the patient by one's normal intonation, introduce oneself, hold the patient's hands, touch the patient gently, talk to the patient about all the measures that had been done for the patient's improvement Then, in the second 5 min of the visit, the visitor again should touch the patient's hands and face, make the patient familiar with the time and place, and In the third set of 5 min, the visitor should touch the patient again, say goodbye, and finally state the time of the next visit.

**Category**

Rehabilitation

**2**

**Description**

In control group did not perform any intervention exception of routin nursing care.

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Besat hospital

**Full name of responsible person**

Ghلام Hossein Falahinia

**Street address**

**City**

Hamadan

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamadan University of Medical Sciences

**Full name of responsible person**

Dr. Heidar Tavilani

**Street address**

Vice-Chancellor of Research and Technology,  
Hamadan University of Medical Sciences, Shaheed Fahmideh Ave

**City**

Hamadan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Hamadan 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**

Department of Medical Surgical Nursing

**Full name of responsible person**

Ghلام Hossein Falahinia

**Position**

Master of nursing

**Other areas of specialty/work**

**Street address**

Department of Medical Surgical Nursing, Nursing and Midwifery School, Hamadan University of Medical Sciences, Shaheed Fahmideh Av

**City**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0439

**Fax**

**Email**

falahinia@umsha.ac.ir

**Web page address**

**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Department of Medical Surgical Nursing

**Full name of responsible person**

Ghلام Hossein Falahinia

**Position**

Master of Nursing

**Other areas of specialty/work**

**Street address**

Department of Medical Surgical Nursing, Nursing and Midwifery School, Hamadan University of Medical Sciences, Shaheed Fahmideh Ave

**City**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0439

**Fax**

**Email**

falahinia@umsha.ac.ir

**Web page address**

## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Hamadan university of medical science

**Full name of responsible person**

Mehdi sahebi

### **Position**

Master of Critical Care Nursing Student

### **Other areas of specialty/work**

### **Street address**

Hamadan University of Medical Sciences, Shaheed Fahmideh Ave

### **City**

Hamadan

### **Postal code**

### **Phone**

+98 81 3837 8097

### **Fax**

### **Email**

mehdi-sahebi@hotmail.com

### **Web page address**

## **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*