

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The effect of dyang sensory stimulation on the pain and restlessness of patients admitted to intensive care units

#### Protocol summary

##### Study aim

Determining the effect of dyang sensory stimulation on pain and restlessness of patients admitted to ICU wards of Bahonar hospital in Kerman, 1398-1397

##### Design

This study was performed in 60 patients admitted to Bahonar Hospital in a simple randomized double blind measure of pain and restlessness in patients with thirty patients in the intervention group and thirty patients in the control group

##### Settings and conduct

This study is a randomized, double blind clinical trial performed on patients admitted to intensive care units of Bahonar Hospital in Kerman. Sensory stimulation based on Dyang's table includes visual, auditory, olfactory, tactile and motor stimulation. Patients in the intervention group receive sensory stimulation twice a day for six days. The control group is under routine care. In the intervention group, the patient's pain was measured by the BPS criteria and restlessness with the Rass criterion before and 15 minutes after sensory stimulation by someone other than the researcher. In this study, patients because of low conscious and evaluator did not know about control group or intervention group

##### Participants/Inclusion and exclusion criteria

Age between 18-60 year- There aren't numerous fracture in limbs and thorax -The level of conscious is between 5 -8

##### Intervention groups

Patients admitted in ICU wards of Bahonar Hospital in Kerman

##### Main outcome variables

pain and restlessness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150519022320N21**

Registration date: **2019-11-02, 1398/08/11**

Registration timing: **retrospective**

Last update: **2019-11-02, 1398/08/11**

Update count: **0**

##### Registration date

2019-11-02, 1398/08/11

##### Registrant information

###### Name

Tayebeh Mirzaei

###### Name of organization / entity

Rafsanjan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-21, 1398/01/01

##### Expected recruitment end date

2019-09-22, 1398/06/31

##### Actual recruitment start date

2019-03-21, 1398/01/01

##### Actual recruitment end date

2019-08-18, 1398/05/27

##### Trial completion date

2019-08-18, 1398/05/27

##### Scientific title

The effect of dyang sensory stimulation on the pain and restlessness of patients admitted to intensive care units

##### Public title

The effect of sensory stimulation on the pain and restlessness of patients admitted to intensive care units

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Age between 18-60 years old There aren't numerous fracture in limbs and thorax The level of consciousness is between 5 -8

#### **Exclusion criteria:**

Death Starting a continuous infusion of sedative medicine for the patient

### **Age**

From **18 years** old to **60 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

- Participant
- Outcome assessor

### **Sample size**

Target sample size: **60**

Actual sample size reached: **4**

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

Randomized

### **Randomization description**

60 patients are selected for entry criteria. Subsequently, according to the random block method, people are divided into two groups of 30 patients, intervention group and control group.

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

Double blinded

### **Blinding description**

In this study, patients and researcher colleague do not aware of the type of group. Patients do not aware of their type of group because of decreased level of consciousness. The researcher colleague who measure pain and restlessness in both groups do not aware whether the Patient receive sensory stimulation (intervention group) or not (control group).

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Rafsanjan University of Medical Sciences

##### **Street address**

Emam Ali Blv, Central Organization of the Central Organization of Medical Sciences

#### **City**

Rafsanjan

#### **Province**

Kerman

#### **Postal code**

7718174715

#### **Approval date**

2019-03-17, 1397/12/26

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

IR.RUMS.REC.1397.260

## **Health conditions studied**

### 1

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

pain

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

G89

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

Pain, not elsewhere classified

### 2

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

restlessness

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

R45.1

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

Restlessness and agitation

## **Primary outcomes**

### 1

#### **Description**

Sensory stimulation of Dyang

#### **Timepoint**

For maximum of thirty minutes

#### **Method of measurement**

Sensory stimulation table Dyang

## **Secondary outcomes**

### 1

#### **Description**

pain

#### **Timepoint**

Sensory stimulation table Dyang

#### **Method of measurement**

Behavioral Pain scale

### 2

#### **Description**

restless

#### **Timepoint**

Before and fifteen minutes after diang of sensory stimulation

## Method of measurement

Richmond Agitation-Sedation Scale

## Intervention groups

### 1

#### Description

In the intervention group The sensory stimuli of Dyang are exactly based on the sensory arrangement in the Dyang's table, which includes visual, auditory, olfactory, tactile and motor stimulation. Stimulation of vision by turning off the flashlight in front of the patient's eyes for 2 seconds, stimulating the hearing by telling the patient's name and time, place and day near the patient's ears three times, stimulating the smell of cotton be soaked with rose water in the patient's nose for 5 seconds, Stimulation of the touch with hand pressure, massage and rubbing the cotton and gas in to the skin, first on one side of the body and then on the other side, and stimulating the movement by moving the joints of the hands, feet, hands, arms and shoulders by bending and straightening up and down. Alternate hands This intervention continue 6 days for every patient, two times a day and one hour for every time.

#### Category

Treatment - Devices

### 2

#### Description

Control group: In the control group, do not any intervention. routine care is performed

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kerman Shahid Bahonar Hospital

##### Full name of responsible person

Khadije Mohammady

##### Street address

Gharani St. Bahonar Hospital

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bahonarhospitalresearch@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Dr Shamsizade Ali

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#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Ali Ravari

##### Position

Nursing PH.D

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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