Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 beacuse 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 arenot 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

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Name of organization / entity
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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 arenot numerous fracture in limbs and thorax The level of conscious 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 gourp 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
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Sponsors / Funding sources

1

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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
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Nursing PH.D
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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