

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

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mehdi sahebi

Name of organization / entity

Hamadan University of Medical Sciences

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Dr. Heidar Tavilani

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

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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

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

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Position

Master of nursing

Other areas of specialty/work

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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