

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effect of sensory stimulation on physiologic parameters of selected hospitals of Isfahan University of Medical Sciences' critical care patients

Protocol summary

Summary

This study was conducted to determine The effect of sensory stimulation on physiologic parameters of critical care patients. The inclusion criteria were Eighteen to sixty years of age , $12 \geq \text{GCS} \geq 9$, Having hemodynamic stability and Exclusion criteria were Presence of hearing impairment, skin disorders, psychiatric disorder ,life-threatening disease as advanced cancer and renal failer, Create the conditions that needs to emergency Medical or Nursing intervention. Participants were 64 patient hospitalized in intensive care unit that selected using convenience sampling and divided in 2 groups control and intervention. patient's physiologic parameters(systolic blood pressure, diastolic blood pressure, pulse rate and arterial blood oxygen saturation)were measured 10 minutes before intervention and recorded as before intervention physiologic parameters then patient family in intervention group after wearing gown and Slippers and washing hands and rubbing them with antibacterial jel and training about the correct procedure entered to ward and 15 minute Under the supervision of Researcher touched patient and talked with he/her and after 15 minute left the ward. Physiologic parameters were recorded immediately, 10 minutes and 30 minutes after intervention. In control s group Simultaneously without any intervention physiologic parameters were recorded in 0, 27,37 and 57 minute. Intervention was performed twice on day in the morning and afternoon.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013110215241N1**

Registration date: **2013-11-12, 1392/08/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-11-12, 1392/08/21

Registrant information

Name

Mozhegan Naderi

Name of organization / entity

Faculty of Nursing & Midwifery Isfahan University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Science

Expected recruitment start date

2012-11-30, 1391/09/10

Expected recruitment end date

2013-10-17, 1392/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sensory stimulation on physiologic parameters of selected hospitals of Isfahan University of Medical Sciences' critical care patients

Public title

The effect of family communication and touch on unconscious patient

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria : Eighteen to sixty years of age in patients ; admitted to ICU >24 h ; $12 \geq \text{GCS} \geq 9$; Presence of hemodynamic stability: HR = 60-100 , MBP>65mmHg, $\text{o}_2 \text{ sat} > 90\%$; Being available patient family! Pass at least 6 hours from the time of opioid or sedative drugs injection; The patient might be intubated or not.

Exclusion criteria: Addiction with cigarette, opioide or alcohol; Presence of hearing impairment ; Presence of skin disorders; Presence of psychiatric disorder; Presence of life-threatening disease as advanced cancer and renal failer; Dopamin, TNG or Dobutamin infusion during intervention; Create the conditions that needs to emergency Medical or Nursing intervention.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

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

Isfahan University of Medical Science

Street address

Hezarjarib street-Isfahan University of Medical Science

City

Isfahan

Postal code

Approval date

2012-11-27, 1391/09/07

Ethics committee reference number

391317

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

Systolic blood pressure

Timepoint

10 minute before intervention, immediately after intervention, 10 minute after intervention, 30 minute after intervention

Method of measurement

Connected to patient hemodynamic monitoring

2

Description

Diastolic blood pressure

Timepoint

10 minute before intervention, immediately after intervention, 10 minute after intervention, 30 minute after intervention

Method of measurement

Connected to patient hemodynamic monitoring

3

Description

Pulse

Timepoint

10 minute before intervention, immediately after intervention, 10 minute after intervention, 30 minute after intervention

Method of measurement

Connected to patient hemodynamic monitoring

4

Description

Oxygen saturation

Timepoint

10 minute before intervention, immediately after intervention, 10 minute after intervention, 30 minute after intervention

Method of measurement

Connected to patient hemodynamic monitoring

Secondary outcomes

1

Description

Family anxiety

Timepoint

Before and after intervention

Method of measurement

Spielberger State-Trait Anxiety Inventory

2

Description

Patient anxiety

Timepoint

Before and after intervention

Method of measurement

Fase anxiety scale

Intervention groups

1

Description

This intervention is performed in three 5 minute section with two 1 minute intervals and is performed twice on day between 10-12 hours in the morning and between 3-5 hours 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, and wait for 1 min. 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 wait again for 1 min. 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

Other

2

Description

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

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Hojatollah Yousefi

Street address

Sofeh street, Isfahan

City

Isfahan

2

Recruitment center

Name of recruitment center

Ayatollah Kashani hospital

Full name of responsible person

Reza Daryabeigi

Street address

Ayatollah Kashani street, Isfahan

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Science

Full name of responsible person

Dr. Mir Alimohamad Sabzeghabaii

Street address

Isfahan University of Medical Science -Vice chancellor for Research

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Science

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

Faculty of nursing & Midwifery Isfahan University of Medical Science

Full name of responsible person

Mozhegan Naderi

Position

Master of Nursing Student

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