

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of the effect of touch by nurse with touch by the patient himself on vital signs and level of consciousness of patients admitted to intensive care units

Protocol summary

Vital signs, level of consciousness

Study aim

The effect of touching the patient's hand on their level of consciousness and vital signs

Design

This study is a randomized clinical trial with 48 patients in two groups. The touch group by the patient's own hand (first group) and the touch group by the nurse (second group). After the available selection of hospitalized and purpose-based patients, in terms of admission criteria, they are randomly assigned to two groups in equal numbers using quadruple permutation blocks. Blindness for patients due to their lack of consciousness has been investigated and due to the lack of knowledge of the registrar of consciousness and vital signs of the subject in the groups and also a statistical analyst, in fact, this study was designed with two parallel groups, random and double-blind.

Settings and conduct

This randomized clinical trial is performed on patients with impaired level of consciousness (GCS below 8) admitted to intensive care units of Khorasan Razavi (in two groups). In the first group, touch therapy of the face and torso is performed by the patient's own hand, but with the help of a nurse, for six consecutive days and each time for 10 minutes. It takes time. Blinding for patients due to lack of consciousness is practically achieved and does not require special action.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 15-60 years, absence of tactile disorders in different parts of the patient, GCS below 8 Exclusion criteria: dissatisfaction of companions

Intervention groups

The intervention group includes patients who receive sensory stimulation with their own hands. The control group includes patients who receive sensory stimulation through the nurse.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210327050780N1**

Registration date: **2021-12-06, 1400/09/15**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-06, 1400/09/15**

Update count: **0**

Registration date

2021-12-06, 1400/09/15

Registrant information

Name

Khadijeh Sadeghiyan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-22, 1400/07/30

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of touch by nurse with touch by the patient himself on vital signs and level of consciousness of patients admitted to intensive care units

Public title

The effect of touch on vital signs and level of consciousness

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Effect by reducing the level of consciousness with the inclusion criteria of age between 15 to 60 Patients with decreased level of consciousness with GCS inclusion criteria below 8 Patients with decreased level of consciousness with the criterion of the absence of various sensory disorders

Exclusion criteria:

Transfer the patient to other medical centers Having sensory problems

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the research units are selected according to the estimated number of available patients admitted to intensive care units according to the inclusion criteria and in a purposful method. Then, using the quadruple block method, they are randomly assigned to two groups of two touch therapy groups (one group by the patient's own hand with help and the other by the nurse, 24 people in each group). In this way, for the group to be touched by the patient's own hand) with the help of the letter A and for the group to be touched by the nurse's hand, the letter B is considered. Possible modes in the four blocks of six modes include AABB, BBAA, ABAB, BABA, ABBA, BAAB, each mode is written on a card and the cards are assigned the number one to six. Then, using a dice, one of the six possible modes is selected and based on that, the selected patients are assigned to two relevant groups. This process continues until the sample size is completed.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Are sensory stimuli performed by patients themselves more effective than sensory stimuli performed by the nurse on the patient? In addition, at present, the policy of meeting in the private sector in the country has many restrictions. In most medical centers, sensory stimulation is performed by nurses and also the role of the patient himself in comparison with nurses in performing sensory stimulation has not been measured in a separate study in Iran. Vital signs and level of consciousness of patients admitted to special wards are not mentioned and this indicates the research gap and knowledge in this regard.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

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Razavi Khorasan

Postal code

9518951607

Approval date

2021-03-14, 1399/12/24

Ethics committee reference number

IR.GMU.REC.1399.135

Health conditions studied**1****Description of health condition studied**

Loss of consciousness

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Level of conciosness

Timepoint

Touch for six consecutive days, each time for 10 minutes in the morning and evening shifts.

Method of measurement

Glasgow Coma Scale

Secondary outcomes

1

Description

Vital Signs

Timepoint

Control vital signs before and after the intervention on 6 consecutive days in the morning and evening

Method of measurement

Respiratory rate by counting the number of ups and downs of the chest, checking systolic and diastolic blood pressure, heart rate with the vital signs monitoring device Saadat brand model S1600 and oral thermometer is used for temperature.

Intervention groups

1

Description

Intervention group 1: the group that is touched by a nurse.

Category

Treatment - Other

2

Description

Intervention group 2: A group that is touched by the patient herself and with the help of a nurse.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Torbat heydariye Razi and 9-day hospital

Full name of responsible person

Khadijeh Sadeghiyan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Khadijeh Sadeghiyan

Position

Senior Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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