Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

Investigation the effect of verbal communication on the level of consciousness, pain and agitation in patients admitted to Intensive Care Unit

Protocol summary

Study aim
Determining the effect of verbal communication on the level of consciousness, pain and agitation in patients admitted to Intensive Care Unit in Ali-Ebne Abitaleb Hospital in Rafsanjan City in 2019

Design
Two arm parallel-group randomized trial with blinded intensive care and outcome assessment. Patients' level of consciousness, pain, and restlessness will be measured in 35 patients in the intervention group and 35 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 Ali-Ebne Abitaleb Hospital in Rafsanjan. Patients in the intervention group will receive verbal communication twice a day for 14 days. The control group will under routine care. In the intervention group, the patient's level of consciousness is measured by Glasgow Coma Scale (GCS) for level of consciousness, Behavioral Scale for Pain (BPS criteria) and restlessness with the Rass criterion before and 15 minutes after verbal communication 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 15-75 years GCS≤ 8 Traumatic and non-traumatic patients No previous history of brain injury No history of hearing impairment, or hearing loss stabilizing vital signs in patient in the intensive care unit

Intervention groups
Intervention group: Patients in the intervention group receive verbal communication twice a day for one week. Control group: receive routine care.

Main outcome variables
level of consciousness, pain and restlessness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150519022320N22**
Registration date: **2020-05-08, 1399/02/19**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-08, 1399/02/19**
Update count: **0**

Registration date
2020-05-08, 1399/02/19

Registrant information

Name
Tayebeh Mirzaei

Name of organization / entity
Rafsanjan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-28, 1398/11/08

Expected recruitment end date
2021-01-27, 1399/11/08

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigation the effect of verbal communication on the level of consciousness, pain and agitation in patients admitted to Intensive Care Unit

Public title
The effect of verbal communication on the level of consciousness, pain and agitation in patients admitted to Intensive Care Unit

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 15-75 years GCS≤ 8 scale score Traumatic and non-traumatic patients No history of previous brain injury No history of the previous disorder or loss hearing Stabilizing the patient's vital signs in the intensive care unit

Exclusion criteria:
Cranial fractures in the temporal region according to the report CT-Scan Bleeding in this temporal area according to a report CT-Scan

Age
From **15 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
according to the random block method, Persons will be divided into two groups of 35 patients، intervention group and control group. Patients were randomly assigned to 7- 10 person blocks and then the blocks will be divided into two groups and divided into groups.

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 level of consciousness, pain and restlessness in both groups do not aware whether the Patient receive verbal communication (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
2019-03-28, 1398/01/08

Ethics committee reference number
IR.RUMS.REC.1398.189

Health conditions studied

1

Description of health condition studied
consciousness

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Pain

ICD-10 code
G89

ICD-10 code description
Pain, not elsewhere classified

3

Description of health condition studied
Restlessness

ICD-10 code
R45.1

ICD-10 code description
Restlessness and agitation

Primary outcomes

1

Description
level of consciousness

Timepoint
Before and fifteen minutes after intrvention

Method of measurement

Glasgow Coma Scale (GCS)

2

Description
pain
Timepoint
Before and fifteen minutes after intrvention
Method of measurement
Behavioral Pain scale

3

Description
restless
Timepoint
Before and fifteen minutes after intrvention
Method of measurement
Richmond Agitation-Sedation Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Verbal communication is based on the nurse's relationship with the patient, including the nurse's introduction, Inform the patient about the present situation, time and place, Introducing a physician or physicians, a brief description of what has happened to the patient, a brief account of what happened to the patient, the reason for being admitted to ICU, expressing the patient's peripheral status, actions were taken by the patient to expedite the recovery process, describing the patient's current condition, statement of actions to be taken in the next shift or days following the patient, instilling hope and striving for recovery, If necessary, ask patient to cooperate with treatment team, tolerate specific devices Ventilator wrap, brief description of ICU, and patient coordination with therapies and treatment modalities, how to communicate with nurses, and symptoms of recovery, the purpose of medical and nursing care, and measures to improve early and return the patient to the family. The intervention group will have verbal communication for at least 15-20 minutes for one week and twice daily (evening and night shift). Verbal communication will be made with the voice of a trained ICU nurse.
Category
Treatment - Other

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
Ali-Ebne Abitaleb Hospital in Rafsanjan City
Full name of responsible person
Fatemeh Mohammad Akbari
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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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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