Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Survey of the effect of family members voice on level of consciousness of comatose patients admitted to the Intensive Care Unit

Protocol summary

Summary

This study is a clinical trial.The aim of this study is to survey of the effect voices of family members on level of consciousness comatose patients of with acute subdural hematoma caused by head trauma . Number of research Samples 40 brain injury patients with acute subdural hematoma admitted to the Intensive Care Units of Yazd SHahid Rahnemoon Hospital is. sampling is performed over a period of 6 months and they will be select randomly by the investigator, patients in the intervention and control groups (each n = 20) will be. Inclusion criteria is included patients with of 75-15 years, of both sexes with GCS less than or equal to 8 at least 24 hours after symptoms have hemodynamic stabilization. Exclusion criteria is included a history of head injury, impairment or hearing loss, bleeding from the ear or nose,Skull base fractures, has a history of drug abuse. Comatose patients, then ensure that inclusion criteria and obtaining informed consent in first-degree family members intended to stabilize the and At least 24 hours after hemodynamic signs are stabilized can be studied. The intervention group received a 10- day, twice daily in the morning and night shifts for 15-5 min tape -recorded voice of a loved one patient in the patient 's family (with the patient's family) known content by MP3 Player and by placing the headphones on his ears and auditory stimulation is and Before and after each auditory stimulation (four times daily) Glasgow Coma Scale score will be determined by the research assistant.In the control group without stimulation with sound family intervention group with the same time intervals (four times daily) Glasgow Coma Scale score of patients is measured. finally GCS scores before and after the intervention and control groups will be identified and will be analyzed

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013110415280N1**
Registration date: **2014-02-11, 1392/11/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-02-11, 1392/11/22

Registrant information

Name
Manijeh SHahriary
Name of organization / entity
Yazd SHahid Sadoughi University Of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 35 1622 2843
Email address
m_kalan13@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Yazd SHahid Sadoughi University of Medical Sciences

Expected recruitment start date

2013-10-22, 1392/07/30

Expected recruitment end date

2014-04-19, 1393/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of the effect of family members voice on level of consciousness of comatose patients admitted to the

Intensive Care Unit

Public title
the effect of family members voice on level of consciousness of comatose patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria : patients with of 75-15 years; of both sexes; with GCS less than or equal to 8 at least 24 hours after symptoms have hemodynamic stabilization.
Exclusion criteria : a history of head injury and impairment or hearing loss; bleeding from the ear or nose; Skull base fractures; as a history of drug abuse.
Age
From **15 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Yazd SHahid Sadoughi University Of Medical Sciences
Street address
Building No. 2, Bahonar Square, Yazd
City
Yazd
Postal code
Approval date
2013-10-21, 1392/07/29
Ethics committee reference number
141434

Health conditions studied

1

Description of health condition studied
coma
ICD-10 code
s06.5
ICD-10 code description
Traumatic Subdural Haemorrhage

Primary outcomes

1

Description
Level of Consciousness
Timepoint
Before and after the intervention
Method of measurement
Glasgow Coma Scale

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group receive a 10- day, twice daily in the morning and night shifts for 15-5 min tape -recorded voice of a loved one patient in the patient 's family (with the patient's family) known content (patient notification to person, time, place , brief events that occurred in , repeating the name of the patient at least three times during the recording, expressing fond memories and termination bar with Statement of expressions of patients to return to his family) by MP3 Player and by placing the headphones on his ears and auditory stimulation is and Before and after each auditory stimulation (four times daily) Glasgow Coma Scale score will be determined by the research assistant during any intervention by the research assistant refused to touch the patient. It 's the sound of a loved one in the family by MP3 Player device model Marshal will be recorded by the investigator in a separate room in the hospital.
Category
Rehabilitation

2

Description
In the control group without stimulation with sound family intervention group with the same time intervals (four times daily) Glasgow Coma Scale score of patients is measured.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Yazd SHahid Rahnemoon Hospital
Full name of responsible person
Manijeh SHahriary Kalantary
Street address
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd SHahid Sadoughi University of Medical Sciences
Full name of responsible person
Hossein Tavangar
Street address
Buali street, shahid Sadoughi School of Nursing Midwifery, Safaieh, Yazd
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd SHahid Sadoughi 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
Yazd SHahid Sadoughi University of Medical sciences
Full name of responsible person
Manijeh SHahriary Kalantary
Position
critical Care Nursing master Student
Other areas of specialty/work
Street address
Building No.2, Bahonar Square, Yazd
City
Yazd
Postal code
Phone
+98 35 1824 1755
Fax
+98 82 49705
Email
m_kalan13@ssu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd SHahid Sadoughi School of Nursing - Midwifery
Full name of responsible person
Hossein Tavangar
Position
Assistant
Other areas of specialty/work
Street address
Buali street, Safaieh, Yazd
City
Yazd
Postal code
Phone
+351 8241755
Fax
Email
tavangar@ssu.ac.irtavangar11@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Yazd SHahid Sadoughi University Of Medical Sciences
Full name of responsible person
Manijeh SHahriary Kalantary
Position
critical Care Nursing master Student
Other areas of specialty/work
Street address
Building No.2, Bahonar Square, Yazd
City
Yazd
Postal code
Phone
+351 7240171
Fax
Email
Web page address
www.ssu.ac.ir

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