

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of Quran voice on the level of consciousness in comatose patients in Intensive Care Unit

Protocol summary

Summary

Objective: To determine the effect of Quran voice on the level of consciousness in anesthetized patients that admitted to the intensive care unit/ Study: randomized, double-blind, placebo-uncontrolled, single-center/ a) Study population: anesthetized patients that hospitalized in the intensive care unit of the complex of martyr modarres hospital in saveh city/ Inclusion criteria: 1. level of consciousness from 3 to 7 on the criteria of the Glasgow coma scale, for 48 hours - 2. Age of 18 to 65 years - 3. No drastic change in shape of face, after severe trauma - 4. Islamic Belief/ Exclusion criteria: 1. Before the tenth day of discharge from the intensive care unit - 2. After 24 hours of surgery - 3. Fatal/ Sample size: 66/ B) intervention study: The effect of Quran voice on the level of consciousness in anesthetized patients that admitted to the intensive care unit/ C) Study time: from the beginning of March 2017 to the end of April Year 2017/ D) The primary outcome: a complete lack of awareness (consciousness between 3 to 7)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122331522N1**

Registration date: **2017-01-18, 1395/10/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-01-18, 1395/10/29

Registrant information

Name

Vahid Naseri Salahshour

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tehran University of Medical Sciences and Health Services

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-04-19, 1396/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Quran voice on the level of consciousness in comatose patients in Intensive Care Unit

Public title

The effect of Quran sound on consciousness in comatose patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: - level of consciousness from 3 to 7 on the criteria of the Glasgow coma scale, for 48 hours. - Age of 18 to 65 years - No history of hospitalization in ICU - No drastic change in shape of face, after severe trauma - The absence of underlying disease diagnosed as tuberculosis, cancer and hepatitis - Islamic beliefs/ Exclusion criteria: - Before the tenth day of discharge

from the intensive care unit - Transfer of patients to other health centers - After 24 hours of surgery - Reluctance of patients to continue research fellows - Fatal

Age

From **17 years** old to **64 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Samples using dice randomly placed in two groups (Intervention and Control)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences and Health Services

Street address

Tehran Province, Tehran, District 6, Pour Sina St

City

Tehran

Postal code

1419733171

Approval date

2016-11-15, 1395/08/25

Ethics committee reference number

IR.TUMS.FNM.REC.13951042

Health conditions studied

1

Description of health condition studied

Coma (unconsciousness)

ICD-10 code

R40.2

ICD-10 code description

Coma, unspecified

Primary outcomes

1

Description

level of consciousness

Timepoint

Before intervention, three days after the start of intervention (third day), four days after the first assessment (seventh day), three days after the second assessment (tenth day)

Method of measurement

glasgow coma scale

Secondary outcomes

1

Description

Heart beat

Timepoint

During the intervention, immediately after intervention

Method of measurement

Beat per minute

2

Description

ECG changes

Timepoint

During the intervention, immediately after intervention

Method of measurement

Electrocardiogram

Intervention groups

1

Description

Control group: daily care depending on the needs of patients in the control group (similar with intervention group) is executed and the samples from both groups were homogeneous as possible, are compared to each.

Category

Other

2

Description

Intervention Group: The intervention group patients once daily for 20 minutes at a time for up to ten days Listen to Quran sound (ostad shahryar)that played through the headphones. Audio player and headphones produced by China and manufactured by Samsung company

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

The ICU of Hospital complex of modarres martyr,
Saveh University of Medical Science/

Full name of responsible person

Vahid Naseri Salahshour, MSc of Nursing Education in
Medical Surgical Field

Street address

saveh, shahid beheshti blv, mehr st, avisa residential
complex, fifth floor, the eighteenth unit

City

Saveh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Nursing and Midwifery
School of Tehran University of Medical Science

Full name of responsible person

Dr. Ziba Taghizadeh (Assistant Professor and PhD in
Reproductive Health), Vice Chancellor for resear

Street address

Tehran, Nosrat St, Tohid Sq, School of Nursing and
Midwifery

City

Tehran

Grant name

-

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Nursing and Midwifery
School of Tehran 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

Arak University of Medical Science

Full name of responsible person

vahid naseri salahshour

Position

MSc of Nursing Education in Medical Surgical Field

Other areas of specialty/work**Street address**

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Name of organization / entity

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Services

Full name of responsible person

vahid naseri salahshour

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Web page address**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