Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of favorite music on physiological and behavioral parameters of pain in unconscious patients admitted to Intensive care unit

Protocol summary

Summary

This study is a blind clinical trial will be done on 72 patients (cannot able to communicate and report pain) who admitted to intensive care unit of Tehran University of Medical Sciences Hospitals. If the patients have all inclusion criteria, after obtaining consent from their families, will be enrolled in the study. The patients randomly allocated into two groups, intervention and control. Ten minutes before the intervention, the pain will be measured and recorded by using CPOT, vital signs (systolic pressure, diastolic pressure, mean arterial pressure and pulse rate) and arterial blood oxygen saturation with checking the monitoring system, in the groups. The intervention group will listen to selected music using MP3 player with headphones for 30 minutes for three days. Thirty minutes after the intervention, the vital signs and pain will be assessed. Moreover, during the intervention, arterial blood oxygen saturation and vital signs will be assessed every 10 minutes in both of groups. In the control group will not be done any intervention during the 30 minutes and they only must be rest during this periods. The primary outcomes of the study will be vital signs, oxygen saturation and behavioral pain score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105301599N11**
Registration date: **2011-07-24, 1390/05/02**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-07-24, 1390/05/02

Registrant information

Name
Mitra Zolfaghari

Name of organization / entity
Tehran University of Medical Sciences and Health Services

Country
Iran (Islamic Republic of)

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+98 21 6692 7171

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zolfaghm@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, Nursing and Midwifery Care Research Center.

Expected recruitment start date

2011-08-01, 1390/05/10

Expected recruitment end date

2011-12-22, 1390/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of favorite music on physiological and behavioral parameters of pain in unconscious patients admitted to Intensive care unit

Public title

The effect of music on pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 18 to 50 years old; Hospitalized in ICU for the first time; Inability to verbally report pain;

Existence of pain in patients by CPOT; Lack of hearing problems; Quadriplegia exclusion criteria: Increasing the dose of sedative and anesthetic drugs during the study; Neuromuscular blocking; Brain dead; Reluctance to cooperating the patient's family

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

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

CENTER OF NURSING AND MIDWIFERY RESEARCH

Street address

CENTER OF NURSING AND MIDWIFERY RESEARCH, TEHRAN UNIVERSITY OF MEDICAL SCEINCES FACUITY OF NURSING AND MIDWIFERY, SQUARE OF THOHID, TEHRAN

City

TEHRAN

Postal code

Approval date

2011-07-15, 1390/04/24

Ethics committee reference number

*****

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

R52.9

ICD-10 code description

Generalized pain NOS

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Ten minutes before the intervention, each 10 minutes during the intervention (three times), 30 minutes after intervention

Method of measurement

observation of Monitoring

2

Description

behavioral parameters of pain

Timepoint

10 minutes before intervention 30 minutes after intervention

Method of measurement

Measurement by critical pain observation tool(CPOT)

3

Description

Systolic blood pressure

Timepoint

Ten minutes before the intervention, each 10 minutes during the intervention (three times), 30 minutes after intervention

Method of measurement

observation of Monitoring

4

Description

Mean arterial pressure

Timepoint

Ten minutes before the intervention, each 10 minutes during the intervention (three times), 30 minutes after intervention

Method of measurement

observation of Monitoring

5

Description

Pulse

Timepoint

Ten minutes before the intervention, each 10 minutes during the intervention (three times), 30 minutes after intervention

Method of measurement

observation of Monitoring

6

Description

Arterial oxygen saturation(sao2)

Timepoint

Ten minutes before the intervention, each 10 minutes during the intervention (three times), 30 minutes after

intervention

Method of measurement

observation of Monitoring

Secondary outcomes

empty

Intervention groups

1

Description

Resting in bed for 30 minutes without any intervention

Category

N/A

2

Description

Listening to music with headphones. Intervention time during three consecutive days for 30 minutes at PM 3-4:30

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences

Full name of responsible person

Street address

City

Tehran

3

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nursing and Midwifery Care Research Center,Tehran University of Medical Sciences

Full name of responsible person

Mitra Zolfaghari

Street address

Nursing and Midwifery Care Research Cente, Tehran University of Medical Sciences, FACUITY OF NURSING AND MIDWIFERY, EAST NOSRAT ST, SQUARE OF THOHID, THERAN, IRAN

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Nursing and Midwifery Care Research Center,Tehran 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mitra Zolfaghari

Position

PhD

Other areas of specialty/work

Street address

Nursing and Midwifery Care Research Cente, FACUITY OF NURSING AND MIDWIFERY, TEHRAN UNIVERSITY OF MEDICAL SCEINCES, EAST NOSRAT ST, THOHID SQ, TEHRAN, IRAN

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Web page address

Person responsible for updating data

Contact

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