

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Investigating effects of sound frequencies on pain, comfort and anxiety levels in venous-arterial blood sampling, intramuscular injection, and venous intra-vascular access process

Protocol summary

Study aim

Determining the effects of sound frequencies on pain, comfort, anxiety level and hemodynamic changes in the processes of venous-arterial blood sampling, intramuscular injection and intravenous access.

Design

This clinical trial study was conducted on 300 patients with control and intervention (parallel) groups in a randomized and double-blind manner and in phase 3. The software was used for randomization.

Settings and conduct

Patients referred to Imam Reza and Imam Khomeini Hospital in Kermanshah who needed blood sampling and intramuscular injection. Patients were randomly divided into intervention and control groups. Only in the intervention groups, sound frequency stimulation is performed by headphones on the ear for patients at the same time as the needle tip is inserted. In order to conduct a double-blind study, the patients and the colleague recording the results were not aware of the grouping and type of intervention.

Participants/Inclusion and exclusion criteria

Patients requiring blood sampling and intramuscular injection who experience acute pain.

Intervention groups

In a control group; during each of the procedures, the patients do not receive any stimulus or pain relief, and the procedure is performed according to the routine of the department and the noise level of the environment. In another control group; during each of the procedures, passive wireless headphones are placed on both ears of the patients so that the intensity of the ambient sound is less than 5 dB, and the patients in this group do not receive any sound stimuli. In intervention groups, sound stimulation with frequencies of 5, 10, 15, 20, 30, 40, 50 ,100Hz: wireless headphones are placed on both ears one minute before each procedure. Sound stimulation

with different frequencies is performed from one minute before the procedure until its completion.

Main outcome variables

pain; stress; comfort

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240123060780N2**

Registration date: **2024-02-19, 1402/11/30**

Registration timing: **prospective**

Last update: **2024-02-19, 1402/11/30**

Update count: **0**

Registration date

2024-02-19, 1402/11/30

Registrant information

Name

Rasoul Kavyannejad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-13, 1403/01/25

Expected recruitment end date

2025-04-14, 1404/01/25

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating effects of sound frequencies on pain, comfort and anxiety levels in venous-arterial blood sampling, intramuscular injection, and venous intra-vascular access process

Public title
Effect of sound frequencies on pain level

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Full consciousness Literacy, reading, writing Verbal ability and healthy vision The skin of the study area should be healthy No peripheral edema in the intervention area .
Exclusion criteria:
Addiction Taking sedatives and anesthetic during the last 24 hours Having a pacemaker and implantable cardiac device and defibrillators History of diabetes Patient restlessness

Age
From **25 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization of the samples in this study is done by computer software. By the software, a random sequence of letters A, B, C, D, E, F, G, H, I, G is assigned to the intervention and control groups. . In the output of the software, blocks are created with a sequence of 8 and 10 random letters (each letter is considered for a group). Then these obtained blocks are placed in sealed envelopes. Before starting the study, one of the researchers opens one of the envelopes and finally, according to the sequence of letters, the patient is placed in one of the intervention or control groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
In control group 1; Headphones are placed on the patient's ear. But the headphones have no function, and the patient is able to hear the surrounding sounds naturally through the holes made on the ear part of the headphones. In control group 2; Healthy headphones but without sound function are placed on the patient's ear so

that he cannot hear the surrounding sounds. In the intervention groups; Healthy headphones with sound function with a specific frequency are used. Due to the identical appearance of the interventions and the patient's lack of information about the grouping and type of stimulation intervention frequency, the patients were blinded to the intervention. Blood sampling and intramuscular injections are done by the co-colleague. Audio frequency was applied through headphones and audio frequency settings were done through Bluetooth headphones. The other colleague who registers the variables does not know how to group and the type of frequency received by the patients.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

Street address
No. 2 Central Building, Kermanshah University of Medical Sciences, Shahid Beheshti Street, Kermanshah, Iran

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2024-01-30, 1402/11/10

Ethics committee reference number
IR.KUMS.REC.1402.634

Health conditions studied

1

Description of health condition studied
Pain

ICD-10 code
G89.1

ICD-10 code description
Acute pain, not elsewhere classified

Primary outcomes

1

Description

Pain

Timepoint

The pain level is measured immediately after the procedure and also in 1, 3 and 5 minutes after the procedure is completed.

Method of measurement

The visual analog scale

2

Description

Comfort level

Timepoint

It is measured in 5 minutes after each procedure (injection or blood sampling).

Method of measurement

The visual analog scale

3

Description

Stress level

Timepoint

5 minutes after each procedure

Method of measurement

The visual analog scale

Secondary outcomes

1

Description

Heart rate

Timepoint

The heart rate is measured before and after procedure (injection and blood sampling) and also in 1, 3 and 5 minutes after the procedure is completed.

Method of measurement

Using portable pulse oximetry

Intervention groups

1

Description

Control group: during each of the procedures, the patients do not receive any stimulation or analgesia, and the procedure is performed according to the routine of the department and the noise level of the environment.

Category

Placebo

2

Description

Control group: during each of the procedures, passive wireless headphones are placed on both ears of the patients so that the intensity of the ambient sound is less than 5 dB, and the patients in this group do not receive any sound stimuli.

Category

Placebo

3

Description

Intervention group: 5 Hz sound stimulation group: wireless headphones are placed on both ears one minute before each procedure. Sound stimulation with a frequency of 5 Hz is performed from one minute before the procedure until its completion.

Category

Treatment - Devices

4

Description

Intervention group: 10 Hz sound stimulation group: wireless headphones are placed on both ears one minute before each procedure. Sound stimulation with a frequency of 10 Hz is performed from one minute before the procedure until its completion.

Category

Treatment - Devices

5

Description

Intervention group: 15 Hz sound stimulation group: wireless headphones are placed on both ears one minute before each procedure. Sound stimulation with a frequency of 15 Hz is performed from one minute before the procedure until its completion.

Category

Treatment - Devices

6

Description

Intervention group: 20 Hz sound stimulation group: wireless headphones are placed on both ears one minute before each procedure. Sound stimulation with a frequency of 20 Hz is performed from one minute before the procedure until its completion.

Category

Treatment - Devices

7

Description

Intervention group: 30 Hz sound stimulation group: wireless headphones are placed on both ears one minute before each procedure. Sound stimulation with a frequency of 30 Hz is performed from one minute before the procedure until its completion.

Category

Treatment - Devices

8

Description

Intervention group: 40 Hz sound stimulation group: wireless headphones are placed on both ears one minute before each procedure. Sound stimulation with a frequency of 40 Hz is performed from one minute before the procedure until its completion.

Category

Treatment - Devices

9

Description

Intervention group: 50 Hz sound stimulation group: wireless headphones are placed on both ears one minute before each procedure. Sound stimulation with a frequency of 50 Hz is performed from one minute before the procedure until its completion.

Category

Treatment - Devices

10

Description

Intervention group: 100 Hz sound stimulation group: wireless headphones are placed on both ears one minute before each procedure. Sound stimulation with a frequency of 100 Hz is performed from one minute before the procedure until its completion.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

said mohamadi

Street address

Imam Reza Hospital, Parastar boulevard, Sorkhalijeh, Kermanshah

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2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Said mohamadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Said mohamadi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable