

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Diazepam and music premedication effectiveness for management of implant surgery associated pain and anxiety

Protocol summary

Study aim

Comparison of Diazepam and music premedication effectiveness for management of implant surgery associated pain and anxiety

Design

A randomized, placebo-controlled, superiority clinical trial with a parallel-group design, conducted on 60 patients. Randomization was done using simple random allocation via PASS 2021 software.

Settings and conduct

Location: Patients referring to Shahid Sadoughi Dental School, Yazd, during the academic year 1403-1404 (2024-2025). Random grouping will be performed initially. After local anesthesia, the tooth will be extracted using a specific forceps. Implant surgery will be performed as a fresh socket procedure. Implants from the brand DIO (UF) will be used. Patients' anxiety levels will be assessed using the Corah's Dental Anxiety Scale (DAS) before and 30 minutes after either medication administration or listening to music. Pain intensity will be measured using the Visual Analog Scale (VAS) two hours after implant placement in all groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years; requirement for extraction of a tooth between teeth numbers 14 and 24 ; immediate implant placement. Exclusion criteria : Alcohol consumption; drug abuse; use of antidepressant medications; use of benzodiazepines; use of muscle relaxants; drug allergies.

Intervention groups

Control : Patients receive a placebo tablet 30 minutes before surgery. Group 2: Patients receive 10 mg Diazepam 30 minutes before surgery. Group 3: Patients receive a placebo tablet 30 minutes before surgery and then listen to relaxing music.

Main outcome variables

The level of anxiety ;The level of pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221212056786N4**

Registration date: **2025-06-22, 1404/04/01**

Registration timing: **prospective**

Last update: **2025-06-22, 1404/04/01**

Update count: **0**

Registration date

2025-06-22, 1404/04/01

Registrant information

Name

Seyed mohammad Arab farashahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3621 2222

Email address

sm.arab@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-11, 1404/04/20

Expected recruitment end date

2026-01-10, 1404/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Diazepam and music premedication effectiveness for management of implant surgery associated pain and anxiety

Public title

Comparison of the effectiveness of diazepam and music in managing pain and anxiety during implant surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age above 18 years
Need for tooth extraction between teeth numbers 14 and 24
Immediate implant placement
Willingness to participate in the study

Exclusion criteria:

Alcohol consumption
Drug abuse
Use of antidepressant medications
Use of benzodiazepines
Use of muscle relaxants
Drug allergies
Hearing problems
Use of hearing aid
Mood disorders
Severe anxiety
presence of systemic diseases
placement of multiple implants
receiving pterygoid or zygomatic implants
history of previous implant surgeries

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed using the simple random allocation method. First, a random sequence will be generated using PASS 2021 software. The output will be an Excel file containing a sequence of numbers from 1 to 60 and a unique code assigned to each study unit. After generating the random number sequence using the software, the numbers and intervention groups are placed into 60 sealed envelopes. When eligible participants arrive, the envelopes are opened and the individuals are assigned to their respective treatment groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi University of Medical Sciences

Street address

Imam Reza Boulevard, Shahid Sadoughi University of Medical Sciences, School of Dentistry

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2025-01-18, 1403/10/29

Ethics committee reference number

IR.SSU.DENTISTRY.REC.1403.080

Health conditions studied

1

Description of health condition studied

Implant surgery anxiety; Postoperative pain after implant placement; Immediate implant placement

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Patients' anxiety score .

Timepoint

At baseline (before surgery) and 30 minutes after the intervention

Method of measurement

Measured using the Corah's Dental Anxiety Scale (DAS), a validated questionnaire for assessing dental anxiety.

2

Description

Pain intensity

Timepoint

two hours after implant placement

Method of measurement

Measured using the Visual Analog Scale (VAS) for pain.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One 10 mg Diazepam tablet

(Loghman, Tehran, Iran) administered 30 minutes before the start of surgery.

Category

Treatment - Drugs

2**Description**

Intervention group: Patients in this group will take one placebo tablet (Ati Pharmed, Karaj, Iran) 30 minutes before surgery and then listen to calming music. The calming music consists of instrumental tracks and is delivered through Sony WH-CH510 headphones (Sony Corporation, Tokyo, Japan).

Category

Other

3**Description**

Control group: Patients will take one placebo tablet (Atipharmed, Karaj, Iran) 30 minutes before surgery.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Sadoughi Dental School, Yazd

Full name of responsible person

Fatemeh Tamartash

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Imam Reza Boulevard, Shahid Sadoughi Dental School

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

seyed mohammad arab farashah

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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

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

seyed mohammad arab farashahi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Yes, there is a plan to share individual participant data (IPD) that have been de-identified, after the completion of the study. The data to be shared will include variables related to the primary outcomes of the study, such as anxiety scores based on the Corah Dental Anxiety Scale and pain scores based on the Visual Analog Scale (VAS). All identifiable information (such as names, national ID numbers, and patient record numbers) will be removed or coded to ensure complete anonymity. The data will be shared exclusively for scientific and research purposes, and only upon formal request by qualified researchers. Access to the data will be granted to applicants with appropriate ethical approvals, and the files will be shared via the corresponding author's email in Excel or SPSS format.

When the data will become available and for how long

The data will be made available 6 months after the publication of the study results.

To whom data/document is available

Available to academic researchers or faculty members affiliated with universities.

Under which criteria data/document could be used

The data will be available solely for academic and research purposes, including meta-analyses and systematic reviews, under the condition that the users obtain prior ethical approval and acknowledge the original study.

From where data/document is obtainable

mohammad arab farashahi
sma.farashahi_69@yahoo.com

What processes are involved for a request to access data/document

Interested researchers should submit a written request to the corresponding author via email, including a brief description of the research purpose, methodology, and ethical approval. Each request will be reviewed by the study team, and access will be granted upon approval.

Comments