Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Street address
Imam Reza Boulevard,Shahid Sadoughi Dental School

City
Yazd

Province
Yazd

Postal code
8915173149

Phone
+98 35 3724 0171

Email
Dentalresearchjournl@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
seyed mohammad arab farashah

Street address
Shahid Sadoughi University of Medical Sciences, Faculty of Dentistry Imam Reza Blvd., beginning of Dahiyeh Fajr Blvd., Yazd, Iran

City
Yazd

Province
Yazd

Postal code
891573149

Phone
+98 35 3724 0171

Email
Dentalresearchjournl@gmail.com

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

Street address
Faculty of Dentistry, Imam Reza Blvd., Kharat Blvd., Daheh Fajr Blvd., Yazd

City
Yazd

Province
Yazd

Postal code
8914881167

Phone
+98 35 3621 2307

Email
sma.farashahi_69@yahoo.com

Person responsible for scientific 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
Street address
Faculty of Dentistry, Imam Reza Blvd., Kharat Blvd., Daheh Fajr Blvd., Yazd
City
Yazd
Province
Yazd
Postal code
8914881167
Phone
035212307
Email
sma.farashahi_69@yahoo.com

Person responsible for updating data

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
Street address
Faculty of Dentistry, Imam Reza Blvd., Kharat Blvd., Daheh Fajr Blvd., Yazd
City
Yazd
Province
Yazd
Postal code
8914881167
Phone
+98 35 3621 2307
Email
sma.farashahi_69@yahoo.com

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