Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of music and diazepam on anxiety and pain control during and after surgery of the impactedmandibular third molar

Protocol summary

Study aim
Investigating the effect of music and diazepam on anxiety and pain control during and after impacted third molar surgery

Design
Uncontrolled, parallel-group, unblinded, randomized, phase 2 clinical trial on 30 patients.

Settings and conduct
This study will be conducted in the second semester of the academic year 1401-1402 and in a dental clinic. 30 patients who need surgery on both sides of the impacted mandibular third molar teeth will participate in the study. All companies are informed about the goals, advantages and disadvantages of participating in the study, and the satisfactory form of participating in the study is done in all decisions. . In each patient, by the split-mouth method, one impacted mandibular third molar will be randomly operated under the intervention of music and the second impacted third molar of the second mandible will be operated under the intervention of only diazepam tablet. The usual way for pain patients after surgery is to take medicine (acetaminophen) until the pain is cured.

Participants/Inclusion and exclusion criteria
Patients with impacted mandibular third molars are between 18 and 35 years old Patients who do not have lower wisdom teeth and are less than 18 and more than 35 years old

Intervention groups
30 patients who need surgery on both sides of the impacted mandibular third molar teeth will participate in the study. In order to investigate the effect of the interventions, in each patient, by the split-mouth method, one impacted mandibular third molar tooth will be randomly operated under the intervention of music and the second mandibular impacted third molar tooth will be operated on in another surgery under the intervention of only diazepam tablet.

Main outcome variables
Taking sedatives prescribed by the doctor, smoking, history of wisdom tooth surgery, pain level, intensity, age, gender, marital status

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231024059839N1**
Registration date: **2023-10-30, 1402/08/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-30, 1402/08/08**
Update count: **0**

Registration date
2023-10-30, 1402/08/08

Registrant information

Name
Hassan Laljohary

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 58 3151 3303

Email address
h.johary6@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2023-12-11, 1402/09/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of music and diazepam on anxiety and pain control during and after surgery of the impactedmandibular third molar

Public title
The effect of music and diazepam on anxiety and pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with bilateral impacted mandibular third molars
Exclusion criteria:
Age
From **18 years** old to **35 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of North Khorasan University of Medical Sciences
Street address
No. 19, 2 Qiyam St., Bojnoord
City
Bojnurd
Province
North Khorasan
Postal code
9661924851
Approval date
2023-10-22, 1402/07/30
Ethics committee reference number
IR.NKUMS.REC.1402.089

Health conditions studied

1

Description of health condition studied
The impacted third molar of the lower jaw/these teeth are all asymptomatic and in terms of their position and level of surgical difficulty, they are in the IIB group of the Pell and Gregory classification (based on panoramic radiographs).
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The person's pain score in the VASP Questionnaire, the person's anxiety score in the Spielberger Questionnaire
Timepoint
Measurement of pain and anxiety before surgery, during surgery and 24 hours after surgery
Method of measurement
VAS pain questionnaire. Spielberger obsession questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In the first session, the wisdom tooth extraction side (right or left) and the group (diazepam or music) will be determined. On one side, the third molar tooth is buried after taking diazepam, and on the other side, it comes out while listening to the patient's favorite music. At the time of diazepam intervention, the night before surgery, the patient will be prescribed a 5 mg diazepam tablet. On the day of surgery, the patient will be asked to take diazepam 60 minutes before surgery In the next session, when the third molar tooth is impacted, the patients are asked to listen to their favorite music, which has already been informed to the researcher, from the beginning to the end of the surgery. If the surgeon needs to communicate with the patient, the patient will be asked to temporarily stop the music and play it again.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Jawadalameh Dental Clinic
Full name of responsible person

Dr. Pouria Sayad
Street address
Commercial Square, Janbaz Blvd
City
Bojnurd
Province
North Khorasan
Postal code
9661924154
Phone
+98 58 3224 4966
Email
h.johary6@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Dr. Wahida Motamedal Sana'i
Street address
Arkan Road, University of Dentistry
City
بجنورد
Province
North Khorasan
Postal code
9661924521
Phone
+98 58 3726 0047
Email
h.johary6@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bojnourd 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
Bojnourd University of Medical Sciences
Full name of responsible person
Hassan Laljohary
Position
Dental student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
Qiyam Qiyam St. 2, No. 19
City
Bojnurd
Province
North Khorasan
Postal code
9661924125
Phone
+98 58 3151 3303
Fax
Email
h.johary6@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Hassan Laljohary
Position
Dental student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
Qiyam Qiyam St. 2, No. 19
City
Bojnurd
Province
North Khorasan
Postal code
9661925421
Phone
+98 58 3151 3303
Fax
Email
h.johary6@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Hassan Laljohary
Position
Dental student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
Qiyam Qiyam St. 2, No. 19

City
Bojnurd
Province
North Khorasan
Postal code
9661925421
Phone
+98 58 3151 3303
Fax
Email
h.johary6@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available