# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 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**

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Iran (Islamic Republic of)

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**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**
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**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
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Commercial Square, Janbaz Blvd
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Bojnourd University of Medical Sciences
**Full name of responsible person**
Dr. Wahida Motamedal Sana'i
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Arkan Road, University of Dentistry
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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**
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
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## 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