

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of music and diazepam on anxiety and pain control during and after surgery of the impacted mandibular 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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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 impacted mandibular 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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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