

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of post-extraction complications of mandibular impacted third molar with piezosurgery vs. conventional rotary method.

Protocol summary

Study aim

Evaluation of post-operative pain, swelling, trismus and duration of impacted tooth extraction using piezoelectric device in comparison with routine rotary method to inform surgeons to select appropriate method for removal of impacted and partially impacted wisdom teeth.

Design

Clinical trial with control group, parallel groups, double blinded, Randomised.

Settings and conduct

This study performed at Shiraz Dental School, each patient selected to participate in the study, his/her right tooth is randomly removed by one of two piezosurgical or rotary method. Measurements, before the surgery and one, three, five and seven days after surgery are performed by a student colleague. The other tooth will be removed one week later. The patient and student colleague is unaware of the method of each side. In rotary method, for osteotomy, No.6 round bur, and for the odontomy, a fissure bur is used. In the piezoelectric method, tip No.SG7D for the osteotomy and tip No.SG6D for odontomy are used. After each operation, the patient's pain score sheet is taken at the last session. Postoperatively, the patient will only be prescribed analgesics gelofen 400 mg every 6 hours for a week, as well as a chlorhexidine mouthwash of 0.2% twice daily for 7 days.

Participants/Inclusion and exclusion criteria

Patients between ages of 18 and 35 years old and healthy with bilateral mandibular impacted teeth are included in the study. Smoker, pregnant patients and who do not wish to cooperate are excluded.

Intervention groups

There is a piezosurgery group that one tooth of each patient that removed by the piezoelectric device will place in it. The other tooth of each patient is removed by the usual rotary procedure are placed in the rotary(control) group.

Main outcome variables

pain measurement by VAS; Face swelling measurement with flexible ruler; Trismus presence or absence; Duration of operation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181114041651N2**

Registration date: **2022-11-05, 1401/08/14**

Registration timing: **retrospective**

Last update: **2022-11-05, 1401/08/14**

Update count: **0**

Registration date

2022-11-05, 1401/08/14

Registrant information

Name

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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

2019-07-24, 1398/05/02

Expected recruitment end date

2019-11-27, 1398/09/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of post-extraction complications of mandibular impacted third molar with piezosurgery vs. conventional rotary method.

Public title

piezosurgery vs. conventional rotary in wisdom tooth surgery.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

having bilateral impacted mandibular wisdom tooth age between 18 to 35

Exclusion criteria:**Age**

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each patient has two mandibular wisdom teeth which one of them will be in case group and the other one will be in control group.

Randomization (investigator's opinion)

Randomized

Randomization description

There is a pocket which there are 15 pieces of paper with letter A (for conventional rotary method) and 15 pieces with letter B (for piezosurgery method) in it. For each patient, one piece of paper will be taken that determine the method which is used to remove right side wisdom tooth. After a week, the other side (left) wisdom tooth will be removed by the other method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient doesn't know that his/her tooth removed by which method. The student colleague who assess the consequences doesn't know the method which is used to remove the tooth too.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd.

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Approval date

2019-07-23, 1398/05/01

Ethics committee reference number

ir.sums.rec.1398.547

Health conditions studied**1****Description of health condition studied**

Bilateral impacted mandibular wisdom tooth.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

time of procedure.

Timepoint

during procedure.

Method of measurement

With a smartphone chronometer, from the beginning of incision to the end of final suture.

2**Description**

Trismus: mouth opening less than 20 mm.

Timepoint

one, three, five and seven days after each surgery.

Method of measurement

Using a tongue blade marked 20 mm distance, the incisal edge of the upper left central tooth to the incisal edge of the lower left central tooth is measured.

3**Description**

The amount of pain after each operation.

Timepoint

From day zero to sixth day after each operation.

Method of measurement

By using of Visual Analogue Scale that patient give a score to his/her pain at home.

4**Description**

Amount of face swelling.

Timepoint

Before the operation and on days one, three, five and seven after operation.

Method of measurement

Using a flexible millimeter ruler, the distances between the mandibular angle and four points of the tragus, the lateral cantus of the eye, the anterior nasal spine, and the most prominent part of the chin (pogonion) are measured.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: piezosurgery:30 patients with bilateral mandibular impacted third molar will be selected.In 15 patients impacted third molar will be extracted on right side and in the others on left side by piezosurgery method

Category

Treatment - Surgery

2**Description**

Control group: rotary:30 patients with bilateral mandibular impacted third molar will be selected.In 15 patients impacted third molar will be extracted on right side and in the others on left side by rotary method.

Category

Treatment - Surgery

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

Shiraz dentistry faculty

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

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

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Position

Assistant professor

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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