Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
Ehsan Aliabadi

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 token 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.
City
Shiraz
Province
Fars
Postal code
713451978
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
Hamidreza Masoumi
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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
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Ehsan Aliabadi
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