

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comparison and evaluation of pain, swelling and trismus of mandibular third molar surgery by conventional rotary device and piezoelectric surgery.

#### Protocol summary

##### Study aim

Evaluation of clinical parameters following application of routine rotary device in comparison with peizosurgery device for surgery of extraction of impacted third molar.

##### Design

Randomized clinical trial, double blinded, control group without placebo

##### Settings and conduct

In this study, which will be conducted in Zahedan Dental School, 30 patients with inclusion criteria and without exclusion criteria will be selected. one of studied methods randomly will choose for each side of patient mouth. Patients are recalled for specific follow-up sessions and will measure pain, swelling, and trismus in these sessions.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: a bilateral mandibular impacted third molar with the surgery hardness degree of maximum 7 and the classification of winter at mesioangular or vertical position and in terms of latency level A or B and class I or II in classification of Pell & Gregory; Surgery with hardness degree of 2 and 3 and the maximum difference of 1 between the two sides in terms of the degree of difficulty and same trauma from surgery in both sides of surgery; patient with the ability to fill in a questionnaire and consent Exclusion criteria: patients with history of systemic diseases; surgery hardness above degree of 3

##### Intervention groups

Surgery in Intervention 1 group with the use of conventional rotary osteotomy instrument Surgery in Intervention 2 group with the use of new Piezosurgery osteotomy instrument

##### Main outcome variables

Pain; Swelling; Maximum mouth opening

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180515039664N2**

Registration date: **2020-05-11, 1399/02/22**

Registration timing: **retrospective**

Last update: **2020-05-11, 1399/02/22**

Update count: **0**

##### Registration date

2020-05-11, 1399/02/22

##### Registrant information

##### Name

Sina Hakimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2272 9626

##### Email address

sinahakimi@irimc.org

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-22, 1398/03/01

##### Expected recruitment end date

2019-06-22, 1398/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison and evaluation of pain, swelling and trismus of mandibular third molar surgery by conventional rotary device and piezoelectric surgery.

## Public title

Comparison and evaluation of post-surgical outcome of mandibular third molar surgery by conventional rotary device and piezoelectric surgery.

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Existence of impacted third lower molar in degree of A or B and Class I or II of impaction (Pell & Gregory classification) Conscious consent to participate in the study No decay Absence of any systemic disease No pregnancy or lactation

### Exclusion criteria:

Any factor that prevents the patient from continuing to study

## Age

From **18 years** old to **50 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Flip a coin were used to randomize samples.

## 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

Ethics committee of Zahedan University of Medical Sciences

##### Street address

ZaUMS Main campus, Jenat Boulevard., Zahedan, Sistan and Baluchestan, Iran

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

##### Approval date

2019-10-15, 1398/07/23

##### Ethics committee reference number

IR.ZAUMS.REC.1398.266

## Health conditions studied

### 1

#### Description of health condition studied

Impacted teeth

#### ICD-10 code

K01.1

#### ICD-10 code description

Impacted teeth

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

1st, 3rd, 7th, and 14th day after surgery

#### Method of measurement

VAS pain scale

### 2

#### Description

Trismus

#### Timepoint

1st, 3rd, 7th, and 14th day after surgery

#### Method of measurement

Clinical examination

### 3

#### Description

Trismus

#### Timepoint

1st, 3rd, 7th, and 14th day after surgery

#### Method of measurement

Clinical examinaion

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: Injection of two lidocaine cartridges with the main anesthesia technique involves the use of an alveolar inferior nerve block (IANB) and Long buccally nerve block, then a triangular Fullthickness flap in the second and third molar teeth with a buccally inclination,

followed by surgical osteotomy in control group by NSK . Vmax surgical motor machine, made in Japan (35,000 rpm),to cool the surgical site during the operation, use 250 ml of sterile washing serum and then followed by tooth extraction and silent washing with 40 ml of sterile serum, followed by suturing with a non-absorbent Silk floss of 3-0 by Simple loop suture technique.

**Category**

Treatment - Surgery

**2****Description**

Intervention group: Injection of two lidocaine cartridges with the main anesthesia technique involves the use of an alveolar inferior nerve block (IANB) and Long buccally nerve block, then a triangular Fullthickness flap in the second and third molar teeth with a buccally inclination, followed by surgical osteotomy in test group by Dmetec SurguryStar plus piezo machine made in South Korea,to cool the surgical site during the operation, use 250 ml of sterile washing serum and then followed by tooth extraction and silent washing with 40 ml of sterile serum, followed by suturing with a non-absorbent Silk floss of 3-0 by Simple loop suture technique.

**Category**

Treatment - Surgery

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

Zahedan university of medical sciences

**Full name of responsible person**

Sina Hakimi

**Street address**

College of Dentistry , Eastern Azadegan St. , Zahedan City

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9817699693

**Phone**

+98 54 3344 1814

**Email**

sinahakimi@irimc.org

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Dr. Nourmohammad Bakhshani

**Street address**

ZaUMS Main campus, Jenat Blvd., Zahedan, Sistan

and Baluchestan, Iran

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Phone**

+98 54 3342 5765

**Email**

nmbakhsha@zdmv.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zahedan 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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Mohammadali Fatehi MARj

**Position**

Dentistry student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

College of Dentistry , Eastern Azadegan St. Zahedan city

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9817699693

**Phone**

+98 54 3329 5715

**Email**

m.ali.f.m1993@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Sina Hakimi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

East Azadegan St. - Kooye tir andazi - Zahedan

College of Dentistry

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9817699693

**Phone**

+98 54 3329 5715

**Email**

sinahakimi@irimc.org

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Mohammadali Fatehi MARj

**Position**

Dentistry student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

College of Dentistry , Eastern Azadegan St. Zahedan  
city

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9817699693

**Phone**

+98 54 3329 5715

**Email**

m.ali.f.m1993@gmail.com

**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