

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

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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

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

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Specialist

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Latest degree

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Other areas of specialty/work

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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