

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

A clinical trial to compare the effectiveness of pizopuncture with conventional technique on periodontal condition and discomfort in patients with exposed maxillary palatal impacted canines

Protocol summary

Study aim

To compare the effectiveness of pizopuncture with conventional technique on periodontal condition and discomfort in patients with exposed maxillary palatal impacted canines

Design

This randomized and double-blind clinical trial with parallel and control groups will be conducted on 20 patients who will be randomly selected using the blocks.

Settings and conduct

Patients with palatally impacted maxillary canines referring to Dental Clinic of Birjand Faculty of Dentistry, Birjand, Iran are chosen as the participants of the study. In this double-blind study, sealed opaque envelopes will be used to conceal the sequencing. Intervention group will receive the ultrasonic surgery and control group will receive conventional technique. The care provider and responsible for data collection are blind to group allocation and the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range of 12-35 years; having unilateral palatal canine; no having history of orthodontic treatment; no having history of trauma in the jaw and face area; no having surgical interventions in the head and face area; having good oral hygiene. Exclusion criteria: Having congenital syndrome or cleft lip and palate; having systemic disease that affects tooth surgery; having dental ankylosis and lack of tooth mobility.

Intervention groups

The intervention group, after aligning the teeth and creating space with a spring opener, the latent canine tooth will be exposed using the scalpel method of the Woodpecker Piezosurgery device. The control group, after aligning the teeth and creating space with a spring opener, the latent canine tooth will be exposed using the conventional milling method.

Main outcome variables

Evaluation of periodontal pocket depth, keratinized gingiva width, the amount of gingival recession and the rate of pain in patient

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230602058366N5**

Registration date: **2024-01-30, 1402/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-30, 1402/11/10**

Update count: **0**

Registration date

2024-01-30, 1402/11/10

Registrant information

Name

Majid Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3243 3002

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2025-01-20, 1403/11/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A clinical trial to compare the effectiveness of pizopuncture with conventional technique on periodontal condition and discomfort in patients with exposed maxillary palatal impacted canines

Public title
The effectiveness of pizopuncture technique on periodontal condition in patients with exposed maxillary palatal impacted canines

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age range of 12-35 years Having unilateral palatal canine No having history of orthodontic treatment; No having history of trauma in the jaw and face area No having surgical interventions in the head and face area Having good oral hygiene
Exclusion criteria:
Having congenital syndrome or cleft lip and palate Having systemic disease that affects tooth surgery Having dental ankylosis and lack of tooth mobility

Age
From **12 years** old to **35 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be enrolled by a research colleague. An individual, blinded to group allocation, will generate a random allocation sequence using SAS computer software before the study begins, ensuring a 1:1 allocation ratio for participant randomization. A block randomization design (block sizes of 4 and 6) will be implemented to guarantee an equal number of participants in each group. Group allocation will be concealed in sequentially numbered, opaque, sealed envelopes, with corresponding envelopes being opened after the enrolled participants have been analyzed. In this study, while the instructor and participants will not be blinded to group allocation, the care provider and individual responsible for data collection will remain blinded.

Blinding (investigator's opinion)
Double blinded

Blinding description

This study is a double-blind in which both researchers and patients are unaware of the allocation. Upon completion of the study and collection of results, the corresponding codes for each patient will be provided to the specialized team. The double-blind nature of the study was maintained by ensuring that the clinical supervisor and the individual responsible for data collection were not privy to the patients' allocation. Consequently, the results will be presented anonymously and in a coded format.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical

Street address

Vice Chancellor for Research and Technology, Birjand University of Medical Sciences, Ghaffari Blvd

City

Birjand

Province

South Khorasan

Postal code

9717811674

Approval date

2023-12-18, 1402/09/27

Ethics committee reference number

IR.BUMS.REC.1402.399

Health conditions studied

1

Description of health condition studied

Palatally impacted maxillary canines

ICD-10 code

K01.1

ICD-10 code description

Impacted teeth

Primary outcomes

1

Description

The periodontal pocket depth

Timepoint

1, 4, 7 and 14 days after intervention

Method of measurement

Based on orthopantomography (OPG) images

2

Description

Keratinized gingiva width

Timepoint

1, 4, 7 and 14 days after intervention

Method of measurement

Measurement of the distance between the marginal gingiva and the mucogingival junction by the Williams probe

3

Description

The amount of gingival recession

Timepoint

1, 4, 7 and 14 days after intervention

Method of measurement

Using a periodontal probe

Secondary outcomes

1

Description

The rate of pain

Timepoint

1, 4, 7 and 14 days after intervention

Method of measurement

Visual analog scale (VAS)

Intervention groups

1

Description

Intervention group: The intervention group, after aligning the teeth and creating space with a spring opener, the latent canine tooth will be exposed using the scalpel method of the Woodpecker Piezosurgery device. Subsequently, the bone surrounding the tooth is punctured on the palatal side to a depth of 3 mm. This procedure is repeated during the second and fourth months post-surgery, without the need for flap removal.

Category

Treatment - Devices

2

Description

Control group: The control group, after aligning the teeth and creating space with a spring opener, the latent canine tooth will be exposed using the conventional milling method.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Clinic of Birjand Faculty of Dentistry

Full name of responsible person

Atefe Ataie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Majid Azizi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The research data obtained from the main outcomes of the study can be shared freely as 'open data'.

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

Under which criteria data/document could be used

The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

From where data/document is obtainable

Majid Azizi provides the data analysis to the applicants via email: majid_67_a@yahoo.com

What processes are involved for a request to access data/document

Applicants can send emails to him and receive a response within a week.

Comments