Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A clinical trial to compare the effectiveness of ultrasonic surgery 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 ultrasonic surgery 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: **IRCT20230602058366N4**
Registration date: **2023-12-11, 1402/09/20**
Registration timing: **prospective**

Last update: **2023-12-11, 1402/09/20**
Update count: **0**

Registration date

2023-12-11, 1402/09/20

Registrant information

Name

Majid Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 56 3243 3002

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azizi@bums.ac.ir

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 ultrasonic surgery with conventional technique on periodontal condition and discomfort in patients with exposed maxillary palatal impacted canines

Public title

The effectiveness of ultrasonic surgery 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
- Outcome assessor

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

2023-10-23, 1402/08/01

Ethics committee reference number

IR.BUMS.REC.1402.319

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.
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
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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
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
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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