

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

A clinical trial to compare the effectiveness of ultrasonic surgery with conventional technique on movement speed and position of exposed teeth in patients with palatally impacted maxillary canines

Protocol summary

Study aim

To compare the effectiveness of ultrasonic surgery with conventional technique on movement speed and position of exposed teeth in patients with palatally impacted maxillary 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; no use of drugs that affect tooth movement; having good oral hygiene; no history of tooth extraction in the previous two months. Exclusion criteria: Having congenital syndrome or cleft lip and palate; having systemic disease that affects tooth movement; having periodontal problems.

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 the amount of angle and position of the hidden tooth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230602058366N2**

Registration date: **2023-11-18, 1402/08/27**

Registration timing: **prospective**

Last update: **2023-11-18, 1402/08/27**

Update count: **0**

Registration date

2023-11-18, 1402/08/27

Registrant information

Name

Majid Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3243 3002

Email address

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 movement speed and position of exposed teeth in patients with palatally impacted maxillary canines

Public title
The effectiveness of ultrasonic surgery on movement speed and position of exposed teeth

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 No use of drugs that affect tooth movement No history of tooth extraction in the previous two months Having good oral hygiene

Exclusion criteria:

Having congenital syndrome or cleft lip and palate Having systemic disease that affects tooth movement Having periodontal problems

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

Gender
Both

Phase
1-2

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be simple randomly assigned to two groups using the blocks and opaque envelopes will be used for concealment

Blinding (investigator's opinion)
Double blinded

Blinding description
The care provider and responsible for data collection are blind to group allocation and the type of intervention.

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

2023-10-09, 1402/07/17

Ethics committee reference number

IR.BUMS.REC.1402.299

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 amount of angle of the hidden tooth

Timepoint

Two months after intervention

Method of measurement

Based on orthopantomography (OPG) images

2

Description

The position of the hidden tooth

Timepoint

Two months after intervention

Method of measurement

Based on orthopantomography (OPG) images

Secondary outcomes

empty

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

Majid Azizi

Street address

Dental Clinic of Birjand Faculty of Dentistry, Pasdaran Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Tooba Kazemi

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research@bums.ac.ir

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

Dentistry

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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Web page address**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