

# 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

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3243 3002

**Email**

majid\_67\_a@yahoo.com

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

Birjand University of Medical Sciences

**Full name of responsible person**

Tooba Kazemi

**Street address**

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

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**Province**

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+98 56 3232 1200

**Email**

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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**Email**

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**Person responsible for scientific 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****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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**Postal code**

9717853577

**Phone**

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**Email**

majid\_67\_a@yahoo.com

**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**