

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### A clinical trial to compare the effectiveness of piezopuncture with conventional technique on movement speed and position of teeth in patients with unilateral palatal canine

#### Protocol summary

##### Study aim

To compare the effectiveness of piezopuncture with conventional technique on movement speed and position of teeth in patients with unilateral palatal canine

##### Design

A randomized and double-blind clinical trial with parallel and control groups conducted on 20 patients. Random allocation will be done using block randomization.

##### Settings and conduct

Patients with unilateral palatal canine 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 piezopuncture technique 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

In the intervention group, after aligning the teeth and creating space with a spring opener, the impacted canine tooth will be extracted using the scalpel method of the Woodpecker Piezosurgery device and a ballista loop. In 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 impacted tooth

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230602058366N3**

Registration date: **2023-12-09, 1402/09/18**

Registration timing: **prospective**

Last update: **2023-12-09, 1402/09/18**

Update count: **0**

##### Registration date

2023-12-09, 1402/09/18

##### 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 piezopuncture with conventional technique on movement speed and position of teeth in patients with unilateral palatal canine

**Public title**

The effectiveness of piezopuncture technique on movement speed and position of 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 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

**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**

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 Sciences

**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.1402.318

**Health conditions studied****1****Description of health condition studied**

Unilateral palatal canine

**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: In 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. One week after the surgery, a ballista loop made from stainless steel wires will be used to extract the impacted tooth.

**Category**

Treatment - Devices

2

**Description**

Control group: In 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

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Dental Clinic of Birjand Faculty of Dentistry, Pasdaran Blvd

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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

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

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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

**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 updating data

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Majid Azizi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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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**