

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### A clinical trial to compare the effectiveness of Multi-Stranded Flexible wires with Single Strand Flat Ribbon wires for lingual fixed retainers after orthodontic treatment

#### Protocol summary

##### Study aim

To compare the effectiveness of Multi-Stranded Flexible wires with Single Strand Flat Ribbon wires for lingual fixed retainers after orthodontic treatment.

##### Design

This randomized and double-blind clinical trial with parallel and two intervention groups will be conducted on 170 patients who will be randomly selected using the random number table.

##### Settings and conduct

Patients with orthodontic treatment 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 I will receive the Multi-Stranded Flexible wires and intervention group II will receive Single Strand Flat Ribbon wires. 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 13-30 years; the patient is in the final stage of orthodontic treatment; fixed orthodontic treatment of the patient with Brackets MBT Mini 0.022; having Class I Malocclusion; having good oral hygiene. Exclusion criteria: Having a deep overbite; having periodontal problems such as bleeding on probing or periodontal pockets depth greater than 3 mm.

##### Intervention groups

The intervention group I will receive Multi-Stranded Flexible wires from American ortho company for anterior teeth of the lower jaw splinting. The intervention group II will receive Single Strand Flat Ribbon wires from American ortho company for anterior teeth of the lower jaw splinting.

##### Main outcome variables

Evaluation of the failure rate of wire, the failure rate of cement, the rate of relapse, band separation and band

separation time

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230602058366N1**

Registration date: **2023-06-06, 1402/03/16**

Registration timing: **prospective**

Last update: **2023-06-06, 1402/03/16**

Update count: **0**

##### Registration date

2023-06-06, 1402/03/16

##### 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

2023-07-23, 1402/05/01

##### Expected recruitment end date

2025-07-23, 1404/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

A clinical trial to compare the effectiveness of Multi-Stranded Flexible wires with Single Strand Flat Ribbon wires for lingual fixed retainers after orthodontic treatment

**Public title**

The effectiveness of wires for lingual fixed retainers after orthodontic treatment

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age range of 13-30 years The patient is in the final stage of orthodontic treatment Fixed orthodontic treatment of the patient with Brackets MBT Mini 0.022 Having Class I Malocclusion Having good oral hygiene

**Exclusion criteria:**

Having a deep overbite Having periodontal problems such as bleeding on probing or periodontal pockets depth greater than 3 mm

**Age**

From **13 years** old to **30 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Care provider
- Outcome assessor

**Sample size**

Target sample size: **170**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be simple randomly assigned to two groups using a random table type 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**

2023-04-17, 1402/01/28

**Ethics committee reference number**

IR.BUMS.REC.1402.010

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

Orthodontic

**ICD-10 code**

C41.0

**ICD-10 code description**

Bones of skull and face

**Primary outcomes****1****Description**

The failure rate of wire

**Timepoint**

3, 6, 9, 12, 15 and 18 months after intervention

**Method of measurement**

Based on the number of wires broken during examination

**2****Description**

The failure rate of cement

**Timepoint**

3, 6, 9, 12, 15 and 18 months after intervention

**Method of measurement**

Based on the number of broken cements during examination

**3****Description**

The rate of relapse

**Timepoint**

3, 6, 9, 12, 15 and 18 months after intervention

**Method of measurement**

Based on the number of teeth moved during examinations

**Secondary outcomes**

## 1

### Description

Band separation

### Timepoint

3, 6, 9, 12, 15 and 18 months after intervention

### Method of measurement

Based on the amount of tooth separation distance during examinations

## 2

### Description

Band separation time

### Timepoint

3, 6, 9, 12, 15 and 18 months after intervention

### Method of measurement

Based on the time of separation of teeth during examinations

## Intervention groups

### 1

#### Description

Intervention group: The intervention group I will receive Multi-Stranded Flexible wires from American ortho company for anterior teeth of the lower jaw splinting.

#### Category

Treatment - Devices

### 2

#### Description

Intervention group: The intervention group II will receive Single Strand Flat Ribbon wires from American ortho company for anterior teeth of the lower jaw splinting.

#### 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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##### Postal code

9717811674

##### Phone

+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

##### Street address

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## Person responsible for scientific inquiries

**Contact**

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## Person responsible for updating data

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Majid Azizi

**Position**

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**Latest degree**

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majid\_67\_a@yahoo.com

## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be 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**