

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

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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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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