# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Sep 2026

## Comparison of the stability of Iranian mini-screw with Korean mini-screw as an orthodontic anchorage: a double-blind randomized clinical trial

### Protocol summary

**Study aim**
To compare the stability of Iranian mini-screw with Korean mini-screw as an orthodontic anchorage

**Design**
This is a double-blind randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

**Settings and conduct**
This study will be performed in the School of Dentistry in Hamadan city on 76 eligible patients who need orthodontic. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Age 15 to 30 years In need of orthodontic treatment Indications for the use of mini-screws Exclusion criteria: Pregnancy Being a smoker

**Intervention groups**
Intervention group 1: Inserting the Iranian mini-screw made by Pouyan Teb Co. with a length of 8 mm and a diameter of 1.6 mm perpendicular to the bone using a manual driver in a predetermined place, then applying force immediately after loading the mini-screw with a force equivalent to 100 to 150 grams. Intervention group 2: Inserting the Korean mini-screw JEIL brand with a length of 8 mm and a diameter of 1.6 mm perpendicular to the bone using a manual driver in a predetermined place, then applying force immediately after loading the mini-screw with a force equivalent to 100 to 150 grams.

**Main outcome variables**
Primary outcome: The degree of stability of Iranian and Korean mini-screws

### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20120215009014N479**
Registration date: **2023-08-01, 1402/05/10**
Registration timing: **prospective**

Last update: **2023-08-01, 1402/05/10**
Update count: **0**

**Registration date**
2023-08-01, 1402/05/10

**Registrant information**

**Name**
Jalal Poorolajal

**Name of organization / entity**
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-08-11, 1402/05/20

**Expected recruitment end date**
2023-12-11, 1402/09/20

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison of the stability of Iranian mini-screw with Korean mini-screw as an orthodontic anchorage: a double-blind randomized clinical trial

**Public title**
Comparison of the stability of Iranian mini-screw with Korean mini-screw
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age 15 to 30 years In need of orthodontic treatment Indications for the use of mini-screw
**Exclusion criteria:**
Pregnancy Being a smoker
**Age**
From **15 years** old to **30 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**
Target sample size: **76**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
The shape, length and diameter of the mini-screws will be the same. Therefore, patients will be unaware of the type of intervention. The person who performs the randomization will be different from the person who examines the patients, so the person who examines the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Hamadan University of Medical Sciences
**Street address**
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
**City**
Hamadan
**Province**
Hamadan
**Postal code**
6517838695
**Approval date**
2023-05-06, 1402/02/16
**Ethics committee reference number**
IR.UMSHA.REC.1402.106

## Health conditions studied

**1**

**Description of health condition studied**
Orthodontic mini-screw device
**ICD-10 code**
Z46.4
**ICD-10 code description**
Encounter for fitting and adjustment of orthodontic device

## Primary outcomes

**1**

**Description**
The degree of stability of Iranian and Korean mini-screws
**Timepoint**
In the first week and then the first, second and third month after treatment
**Method of measurement**
By clinical examination

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group 1: Inserting the Iranian mini-screw made by Pouyan Teb Co. with a length of 8 mm and a diameter of 1.6 mm perpendicular to the bone using a manual driver in a predetermined place, then applying force immediately after loading the mini-screw with a force equivalent to 100 to 150 grams.
**Category**
Treatment - Devices

**2**

**Description**
Intervention group 2: Inserting the Korean mini-screw JEIL brand with a length of 8 mm and a diameter of 1.6 mm perpendicular to the bone using a manual driver in a predetermined place, then applying force immediately after loading the mini-screw with a force equivalent to 100 to 150 grams.

**Category**
Treatment - Devices

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
School of Dentistry in Hamadan city

**Full name of responsible person**
Anahita Morovat

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Hamedan 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**
Hamedan University of Medical Sciences

**Full name of responsible person**
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**Position**
Dentistry Student

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Dentistry

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be 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**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available