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

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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
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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
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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
Anahita Morovat

Position
Dentistry Student

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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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