Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparision of the effect of three different approaches of retention on reopening of extraction space of fixed orthodontic patients in three different retention phases

Protocol summary

Summary

The aim of the present study is to evaluate the effect of three different retention techniques on the amount of reopening of the extraction space at different retention phase intervals in fixed orthodontic patients. The study design is random single-blind. The subjects will consist of patients receiving comprehensive orthodontic treatment in association with the extraction of mandibular first premolars. The inclusion criteria consist of the presence of all the permanent teeth irrespective of third molars and the use of a fixed flexible spiral wire retainer or an extended fixed retainer or a fixed flexible spiral wire retainer along with a Hawley plaque. The exclusion criteria consist of missing teeth and the use of other types of retainers. The study will be carried out on 90 patients in three groups, who are in the final phase of fixed orthodontic treatment. The intervention will consist of administration of an extended fixed retainer in group 1, a fixed flexible spiral wire retainer in group 2, and a fixed flexible spiral wire retainer along with a Hawley plaque in group 3. The primary outcome which will be evaluated is the reopening of extraction space between the mandibular canine and second premolar on both sides, measured in millimeters by a leaf gauge in the patient's oral cavity and on a stone cast at three different time intervals: on the debonding day, and 2 and 6 months after debonding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013113015598N1**
Registration date: **2014-10-25, 1393/08/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-10-25, 1393/08/03

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of the effect of three different approaches of retention on reopening of extraction space of fixed orthodontic patients in three different retention phases

Public title

Evaluating the success of fixed retainers in orthodontic patients

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:the presence of all the permanent teeth irrespective of third molars; the use of a fixed flexible spiral wire retainer or an extended fixed retainer or a fixed flexible spiral wire retainer along with a Hawley plaque Exclusion criteria:missing teeth; the use of other types of retainers
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Science
Street address
Ethics Committee of Tabriz University of Medical Sciences, Vice Chancellor for Research of Tabriz University of Medical Sciences, Tabriz University of Medical Sciences, Golghasht street,Tabriz
City
Tabriz
Postal code
Approval date
2014-08-11, 1393/05/20
Ethics committee reference number
9373

Health conditions studied

1

Description of health condition studied
Evaluating the success of fixed retainers in orthodontic patients
ICD-10 code
Z46.4
ICD-10 code description
Fitting and adjustment of orthodontic device

Primary outcomes

1

Description
reopening of extraction space
Timepoint
debonding day, 2 month and 6 month after debonding day
Method of measurement
In millimetre by leaf guage

Secondary outcomes

empty

Intervention groups

1

Description
Extended fixed retainer in group 1
Category
Other

2

Description
flexible spiral wire retainer
Category
Treatment - Drugs

3

Description
Fixed flexible spiral wire retainer along with a Hawley plaque
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Tabriz University of Medical Sciences
Full name of responsible person
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2

Recruitment center
Name of recruitment center
private office
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3

Recruitment center
Name of recruitment center
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Full name of responsible person
Dr Ali Rafighi
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Sponsors / Funding sources

1

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Tabriz University of Medical Sciences, Golghasht street,Tabriz
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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
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty