

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of orthodontic treatment results stability and gingival health between Hawley and vacuum-formed retainers : randomized clinical trial

Protocol summary

Summary

One of the main challenges for Orthodontists, is maintaining the results of orthodontic treatment. The aim of this study is to compare the orthodontic treatment results stability and gingival health between Hawley and vacuum-formed retainers. In this randomized, single-blind study, 66 patients who have completed the comprehensive orthodontic treatment will be selected randomly and randomly divided into three equal groups of 22 patients. The first group will receive Hawley retainer and the second group vacuum-formed retainer with a thickness of 1 mm and the third group vacuum-formed with a thickness of 1.5 mm retainer. Patients will be matched for age, gender, type of malocclusion, crowding and treatment plan. The study variables are gingival health and orthodontic treatment results stability, which will be evaluated before retainer delivery and six months after delivery, based on Gingival Index and objective grading system, respectively. Inclusion criteria: completion of orthodontic treatment in a proper occlusion; indication of removable retainer. Exclusion criteria: The absence of several teeth and the need to replace them with prosthesis; patients with bruxism; syndromic disease (lip and palate clefts, hemi-facial microsomia); patients with allergy to acrylic resin; patients with temporomandibular joint problems.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021722951N3**

Registration date: **2017-04-28, 1396/02/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-28, 1396/02/08

Registrant information

Name

milad Ghanizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 5921

Email address

milad.ghanizadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Tabriz University Of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-05-31, 1396/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of orthodontic treatment results stability and gingival health between Hawley and vacuum-formed retainers : randomized clinical trial

Public title

The comparison of treatment results of two types of retainers after orthodontic treatment.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: completion of orthodontic treatment in

a proper occlusion; indication of removable retainer.
Exclusion criteria: The absence of several teeth and the need to replace them with prosthesis; patients with bruxism; syndromic disease (lip and palate clefts, hemifacial microsomia); patients with allergy to acrylic resin; patients with temporomandibular joint problems.

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

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 Sciences

Street address

Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz

City

Tabriz

Postal code

Approval date

2017-01-23, 1395/11/04

Ethics committee reference number

IR.TBZMED.REC.1395.1134

Health conditions studied

1

Description of health condition studied

Gingival Health

ICD-10 code

K00

ICD-10 code description

Disorders of tooth development and eruption

2

Description of health condition studied

orthodontic treatment stability

ICD-10 code

K00

ICD-10 code description

Disorders of tooth development and eruption

Primary outcomes

1

Description

Gingival Index

Timepoint

before retainer delivery and six months after delivery

Method of measurement

check list

2

Description

objective grading system method

Timepoint

before retainer delivery and six months after delivery

Method of measurement

check list

Secondary outcomes

empty

Intervention groups

1

Description

The patients of first group(Intervention) will receive Hawley retainer

Category

Other

2

Description

The patients of third group(Intervention) will receive vacuum-formed with a thickness of 1.5 mm retainer.

Category

Other

3

Description

The patients of second group(Intervention) will receive vacuum-formed retainer with a thickness of 1 mm

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Tabriz University of Medical Sciences

Full name of responsible person

DR. Hossein Moslemzadeh

Street address

Research deputy of Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research deputy of 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

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

DR. Somayye Farshidnia

Position

Resident of orthodontics

Other areas of specialty/work

Street address

Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz

City

Tabriz

Postal code

Phone

+98 41 3335 9680

Fax

Email

milad.ghanizadeh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

DR. Somayye Farshidnia

Position

Resident of Orthodontics

Other areas of specialty/work

Street address

Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz

City

Tabriz

Postal code

Phone

+98 41 3335 9680

Fax

Email

milad.ghanizadeh@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

DR Somayye Farshidnia

Position

Resident of Orthodontics

Other areas of specialty/work

Street address

Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz

City

Tabriz

Postal code

Phone

+98 41 3335 9680

Fax

Email

milad.ghanizadeh@gmail.com

Web page address

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