

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of five oral hygiene teaching method in patients with orthodontic appliances (A comparative evaluation)

Protocol summary

Summary

Objectives: determination of the effect of five oral hygiene teaching method in patients with orthodontic appliances. The study population: patients with fixed orthodontic appliances (age range 12 -25 years old) referred to two specialist orthodontic offices located in Hamadan. Design: randomized, single-blind, multicenter. Inclusion criteria: patient should be started their fixed orthodontic treatment during previous 3 months, and no special oral health education at the time of orthodontic treatment, is never given. Patients should have no systemic disease that affect their periodontal conditions; like Diabetes. Also patients must have normal levels of psychological and learning. Exclusion criteria: lack of patient cooperation in principles of education and failure to follow up referral appointment. Target sample size: 125. Setting and conduct: The first group receive orthodontic oral hygiene instruction in the form of face to face training, the second group in the form of face to face training with pamphlet, the third group in the form of face to face training with videotape, the fourth group in the form of face to face training with use of disclosing agent, The fifth group in the form of pamphlet and use of disclosing agent, receive oral hygiene instruction. Time of intervention: one week later orthodontic appliance installation, plaque Index and gingival index will be recorded and oral hygiene instruction will be presented. A week later oral hygiene instruction and one month later oral hygiene instruction, plaque Index and gingival Index will be recorded again. Main outcome measure: plaque Index, gingival Index.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013120915726N1**

Registration date: **2013-12-20, 1392/09/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-20, 1392/09/29

Registrant information

Name

Mojgan Taheri

Name of organization / entity

Hamadan University of Medical Sciences, Faculty of dentistry

Country

Iran (Islamic Republic of)

Phone

+98 81 1835 4016

Email address

m.taheri@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamadan University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-12-21, 1392/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of five oral hygiene teaching method in patients with orthodontic appliances (A comparative evaluation)

Public title

The effect of five oral hygiene teaching method in

patients with orthodontic appliances (A comparative evaluation)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patient should be started their fixed orthodontic treatment during previous 3 months, and no special oral health education at the time of orthodontic treatment, is never given. Patients should have no systemic disease that affect their periodontal conditions; like Diabetes. Also patients must have normal levels of psychological and learning. Exclusion criteria: lack of patient cooperation in principles of education and failure to follow up referral appointment.

Age

From **12 years** old to **25 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **125**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Hamadan University of Medical Sciences, Shahid Fahmideh St, Hamadan, Iran

City

Hamadan

Postal code

65178

Approval date

2013-05-01, 1392/02/11

Ethics committee reference number

16/35/9/276/د/پ

Health conditions studied

1

Description of health condition studied

Gingivitis

ICD-10 code

k05.1

ICD-10 code description

Chronic gingivitis

Primary outcomes

1

Description

Plaque Index

Timepoint

Beginning of the study before oral hygiene instruction, A week later oral hygiene instruction, One month later oral hygiene instruction

Method of measurement

By use of Disclosing Agents Based on Green & Vermillion Plaque Index

2

Description

Gingival Index

Timepoint

Beginning of the study before oral hygiene instruction, A week later oral hygiene instruction, One month later oral hygiene instruction

Method of measurement

By WHO periodontal prob Based on Silness-Löe Gingival Index

Secondary outcomes

empty

Intervention groups

1

Description

Control group: 30 minute face to face oral hygiene instruction, one week later orthodontic appliance installation

Category

Prevention

2

Description

Intervention group 1: 30 minute face to face oral hygiene instruction with Pamphlet, one week later orthodontic appliance installation

Category

Prevention

3

Description

Intervention group 2: 30 minute face to face oral hygiene instruction with videotape , one week later orthodontic appliance installation

Category

Prevention

4

Description

Intervention group 3: 30 minute face to face oral hygiene instruction with use of Disclosing agent , one week later orthodontic appliance installation

Category

Prevention

5

Description

Intervention group 4: oral hygiene instruction with Pamphlet and use of Disclosing agent , one week later orthodontic appliance installation

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammad Karim Soltani doctor's office

Full name of responsible person

Mohammad Karim Soltani, Orthodontists, Assistant Professor

Street address

No 512, Dead End Shbbo, Befor Hotel BuAli, Sinzdahkhane Street, Hamedan, Iran

City

Hamadan

2

Recruitment center

Name of recruitment center

Farhad Jafari Doctor's Office

Full name of responsible person

Farhad Jafari, Orthodontists, Assistant Professor

Street address

Building Moshaver, Khaje Rashid Street, Tomb of Buali Square, Hamedan, Iran

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Hamedan University of

Medical Sciences

Full name of responsible person

Heidar Tavilani

Street address

Vice chancellor for research, Hamadan University of Medical Sciences, Shahid Fahmideh St, Hamadan, Iran

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Hamedan 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

Hamadan faculty of dentistry

Full name of responsible person

Mojgan Taheri

Position

General Dentist

Other areas of specialty/work

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Name of organization / entity

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Full name of responsible person

Mohammad Karim Soltani

Position

Orthodontic

Other areas of specialty/work

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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