

# 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 befor oral hygiene instruction, A week later oral hygiene instruction, One month later oral hygiene instruction

#### **Method of measurement**

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

### **2**

#### **Description**

Gingival Index

#### **Timepoint**

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

#### **Method of measurement**

By WHO periodental 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**

##### **Street address**

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## **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

Hamadan faculty of dentistry

##### **Full name of responsible person**

Mohammad Karim Soltani

##### **Position**

Orthodontic

**Other areas of specialty/work**

**Street address**

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Fahmideh St, Hamadan, Iran

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**Person responsible for updating data**

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**Name of organization / entity**

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**Full name of responsible person**

Mojgan Taheri

**Position**

General dentist

**Other areas of specialty/work**

**Street address**

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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*