

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### comparative evaluation of plaque control following tooth brushing with three different dentifrices and without dentifrice

#### Protocol summary

##### Summary

The present study is used to evaluate the plaque removal efficacy of dentifrice alone during the manual tooth brushing. The study population consisted of 30 student volunteers of dental school of Isfahan medical university. Inclusion criteria: age > 18 years and at least 5 evaluable teeth per quadrant. Exclusion criteria are: orthodontic appliances, removable denture, pregnancy, smoking, periodontitis, any systemic disease that may affect the oral condition and hypersensitivity to the components of the dentifrices. Study design: in a double blinded cross over study 30 subjects, after 48 hours plaque accumulation have brushed randomly with one of the four study methods (brushing with one of the 3 dentifrices that differs with respect to the relative dentin abrasivity (RDA) and without dentifrice), under supervision for 2 minutes. Study was applied in 4 sessions and each subject experienced brushing with all of the methods at the end of the 4th session. Difference in plaque score before and after tooth brushing constitute the plaque reduction. Plaque scores were assessed according to the Quigley and Hein index (Turskey and Loben modification) and they were recorded, analyzed and compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201102234877N3**

Registration date: **2011-09-04, 1390/06/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-09-04, 1390/06/13

#### Registrant information

##### Name

Jaber Yaghini

##### Name of organization / entity

Isfahan University of Medical Sciences and Health Services

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1434 2136

##### Email address

j\_yaghini@dnt.mui.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Isfahan University of Medical Sciences

#### Expected recruitment start date

2010-10-23, 1389/08/01

#### Expected recruitment end date

2011-02-20, 1389/12/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

comparative evaluation of plaque control following tooth brushing with three different dentifrices and without dentifrice

#### Public title

comparison of efficacy of tooth brushing with three different dentifrices and without dentifrice in plaque removal.

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: age > 18 years and at least 5 evaluable

teeth per quadrant; Exclusion criteria: orthodontic appliances; removable denture; pregnancy; smoking; periodontitis; any systemic disease that may affect the oral condition; hypersensitivity to the components of the dentifrices;

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 30

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Isfahan medical university

**Street address**

Periodontology department-Dental faculty-Isfahan medical university-Hezar jerib avenue-

**City**

Isfahan

**Postal code**

81746 -73461

**Approval date**

2010-09-23, 1389/07/01

**Ethics committee reference number**

390148

**Health conditions studied****1****Description of health condition studied**

dental plaque

**ICD-10 code**

K03.6

**ICD-10 code description**

Deposits [accretions] on teeth

**Primary outcomes****1****Description**

Dental plaque

**Timepoint**

Before brushing and after brushing

**Method of measurement**

Disclosing tab

**Secondary outcomes**

empty

**Intervention groups****1****Description**

In the third session, the first step is type 3; ORIGINAL SENSODINE to all of the volunteers and ask them to brush with the new toothbrush and toothpaste for a week in order to be familiar to them. Then ask them not to use any kind of plaque control method for 48 hours. The next step is measuring of plaque and then ask them to brush with their new tooth brush and tooth paste for 2 minutes. In the next step, examiner measures the post brushing plaque and amount of plaque reduction and record it.

**Category**

Prevention

**2****Description**

The last session is asking volunteers not to use any kind of plaque control method for 48 hours. Then measuring of plaque and then ask them to brush with their new tooth brush and without any toothpaste for 2 minutes. In the next step, examiner measures the post brushing plaque and amount of plaque reduction and record it.

**Category**

Prevention

**3****Description**

The first step is giving the same toothbrush (gum 411) and toothpaste type 1; WHITENING POONE to all of the volunteers and ask them to brush with the new toothbrush and toothpaste for a week in order to be familiar to them. Then ask them not to use any kind of plaque control method for 48 hours. The next step is measuring of plaque and then ask them to brush with their new tooth brush and tooth paste for 2 minutes. In the next step, examiner measures the post brushing plaque and amount of plaque reduction and record it.

**Category**

Prevention

#### 4

##### **Description**

In the next session, first step is giving the toothpaste type2; 3DWHITE CREST to all of the volunteers and ask them to brush with the new toothbrush and toothpaste for a week in order to be familiar to them. Then ask them not to use any kind of plaque control method for 48 hours. The next step is measuring of plaque and then ask them to brush with their new tooth brush and tooth paste for 2 minutes. In the next step, examiner measures the post brushing plaque and amount of plaque reduction and record it.

##### **Category**

Prevention

#### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Isfahan University of Medical Sciences

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

Dr jaber yaghini

###### **Street address**

Periodontology department, Dental faculty, Isfahan University of Medical Sciences

###### **City**

Isfahan

#### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

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

Vice chancellor for research, Isfahan University of Medical Sciences

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

Dr Omid Savabi

###### **Street address**

Periodontology Department, Dental Faculty, Isfahan University of Medical Sciences

###### **City**

Isfahan

##### **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, Isfahan 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**

Isfahan University of Medical Sciences

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

Dr Jaber Yaghini

###### **Position**

Assistant professor

###### **Other areas of specialty/work**

###### **Street address**

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#### **Person responsible for scientific inquiries**

##### **Contact**

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

Isfahan University of Medical Sciences

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

Dr Jaber Yaghini

###### **Position**

Assistant professor

###### **Other areas of specialty/work**

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#### **Person responsible for updating data**

##### **Contact**

## **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*