**Clinical Trial Protocol**  
**Iranian Registry of Clinical Trials**  
05 Aug 2019

**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 effect 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 was assessed according to the Quigly 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: | 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 effect the oral condition; hypersensitivity to the components of the dentifrices;

**Age**  
No age limit

**Gender**  
Both

**Phase**
Groups that have been masked
None

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 toothbrush and toothpaste 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 toothbrush and 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 toothbrush and toothpaste 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 type 2: 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 toothbrush and toothpaste 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**

empty

**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**

empty

**Street address**

Periodontology department, Dental faculty, Isfahan University of Medical Sciences

**City**

Isfahan

**Postal code**

81746-73461

**Phone**

+98 31 1434 2136

**Fax**

+98 31 1668 7080

**Email**

j_yaghini@dnt.mui.ac.ir

**Web page address**

www.dnt.mui.ac.ir

### 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**

empty

**Street address**

Periodontology department-Dental Faculty-Isfahan Medical University-Hezar Jerib Avenue

**City**

Isfahan

**Postal code**

81746-73461

**Phone**

+98 31 1434 2136

**Fax**

+98 31 1668 7080

**Email**

j_yaghini@dnt.mui.ac.ir

**Web page address**

www.dnt.mui.ac.ir

### 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