

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Clinical trial of effect of toothbrush wear on plaque control in dental faculty students.

#### Protocol summary

##### Summary

This study will be conducted as a clinical trial. The purpose of this study is investigation of toothbrush wear effect on its clearing power. Inclusion criteria: 1- not to use orthodontic brackets 2- not to use fixed partial dentures 3- not to use antibiotics or any mouthwashes 4- no need for surgery in the mouth during the study, 5- or not suffering from any systemic disease or any factor that can affect the accumulation of plaque on teeth and oral hygiene level. 6- only right handed people are chosen. Exclusion criteria: 1- using of orthodontic brackets 2- using of antibiotics or any mouth washes 3- need for surgery in the mouth during the study 4- using of fixed partial dentures 5- suffering from any systemic disease or any factor that can affect the accumulation of plaque on teeth and oral hygiene level 6- Left handed people. Twenty six subjects will be randomly selected from dental college students. At the beginning of the study subjects will be informed of the purpose, procedural aspects and the period of the study. All participants provided written, and informed consent after complete description of the study. Necessary will be given to them according the Bass technique. Each subject will be provided with a new toothbrush and tooth paste. They will be required to refrain from using any mouthwash or the things for cleaning the teeth during the study. Upon the completion of phase I treatment, we will measure plaque index, if necessary. Individuals will brush for 12 weeks two times per day. Subjects will be called after 6, 9 and 12 weeks for measuring plaque index and wear index. Dental plaque index will be measured and calculated by O'Leary technique. Wear index will be measured according to Rawls. Then the data will be analyzed by using SPSS-18 software, statistical tests ANOVA and Pearson correlation analysis.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201201094877N8**

Registration date: **2012-12-11, 1391/09/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-12-11, 1391/09/21

##### 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

Vice chancellor for research, Isfahan University of Medical Sciences

##### Expected recruitment start date

2012-05-16, 1391/02/27

##### Expected recruitment end date

2012-05-21, 1391/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial of effect of toothbrush wear on plaque control in dental faculty students.

## Public title

Effects of toothbrush wear on plaque control

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: 1- not to use orthodontic brackets 2- not to use fixed partial dentures 3- not to use antibiotics or any mouthwashes 4- no need for surgery in the mouth during the study, 5- or not suffering from any systemic disease or any factor that can affect the accumulation of plaque on teeth and oral hygiene level. 6- only right handed people are chosen. Exclusion criteria: 1- using of orthodontic brackets 2- using of antibiotics or any mouth washes 3- need for surgery in the mouth during the study 4- using of fixed partial dentures 5- suffering from any systemic disease or any factor that can affect the accumulation of plaque on teeth and oral hygiene level 6- Left handed people

## Age

From **21 years** old to **28 years** old

## Gender

Both

## Phase

0

## Groups that have been masked

No information

## Sample size

Target sample size: **26**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics of Isfahan University of Medical Sciences

##### Street address

School of dentistry, Isfahan University of Medical Sciences. Hezar Jerib Street.

##### City

Isfahan

##### Postal code

73461-81746

#### Approval date

2012-06-14, 1391/03/25

## Ethics committee reference number

10/536/3

## Health conditions studied

### 1

#### Description of health condition studied

Gingivitis

#### ICD-10 code

k03.6 , k0

#### ICD-10 code description

Deposits [accretions] on teeth

## Primary outcomes

### 1

#### Description

Plaque index

#### Timepoint

The beginning of study, Sixth Week, Ninth Week and Week Twelve.

#### Method of measurement

After using of the disclosing tablets, the plaque index will be calculated using the following equation:  $100 \times \{(\text{number of teeth} \times 4) / \text{number of stained (non occlusal surfaces)}\}$

## Secondary outcomes

### 1

#### Description

Toothbrush wear

#### Timepoint

Sixth Week, Ninth Week, Twelfth Weeks

#### Method of measurement

All dimensions of brushes will be measured by digital caliper individually. Then brush wear index will be calculated using the following:  $WI = (FLL - BLL) + (FLL - BFL) / BRL$  WI, brush wear index FLL, Brystal length in the surface BLL, Brystal length at the base FFL, Brystal width in the surface BFL, Brystal width at the base BRL, the height of Brystl.

## Intervention groups

### 1

#### Description

This study will be conducted in prospective interventional method. Twenty six participants are selected from dental students. We will use Butler toothbrush and oral disclosures which both of them are made in America, and Crest 7 toothpaste is made in Germany. Individuals will brush for 12 weeks two times a day. At the baseline and at 6, 9, 12 weeks plaque index will measured with O'Leary technique and with use of disclosure tablets. In 6, 9, 12 weeks Toothbrush wear index will measured with

Rawls technique. In the Bass technique toothbrush is placed on the tooth with an angle of about 45 degrees. So brush strings penetrate to the gingival sulcus. Then will given short - range vibrating moves in the anterior - posterior toothbrush. In every area of the teeth, twenty moving is recommended. In the palatal and lingual maxillary and mandibular anterior teeth due to space constraints, the toothbrush put vertically and teeth are cleaned individually with tip. In occlusal surfaces, toothbrush placed horizontally and with low range of back - forward motions cleaning operation is carried

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dental School

##### Full name of responsible person

Saeid Poursaadat

##### Street address

School of dentistry, Isfahan University of Medical Sciences. Hezar Jerib Street.

##### 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

Doctor Omid Savabi

##### Street address

School of dentistry, Isfahan University of Medical Sciences. Hezar Jerib Street.

##### 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

Saeid Poursaadat

##### Position

Medical student / doctoral student dentistry

##### Other areas of specialty/work

##### Street address

School of dentistry, Isfahan University of Medical Sciences. Hezar Jerib Street.

##### City

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##### Postal code

##### Phone

+98 31 1792 2870

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##### Email

Saeid\_P22@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Full name of responsible person

Doctor Ahmad Moghareh Abed

##### Position

Specialty in periodontics

##### Other areas of specialty/work

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##### Web page address

## 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*