

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Comparative evaluation of clinical efficacy of manual Classic and manual Superbrush toothbrushes in plaque removing from the teeth surface of students

#### Protocol summary

##### Summary

**Objectives:** The purpose of this study is to compare the clinical efficacy of manual Classic and manual Superbrush toothbrushes on plaque and bleeding indices. **Design:** This clinical trial will be conducted on 30 volunteer dental students of dental school of Kerman medical university. After taking an informed consent, patients will be randomly divided into two groups with simple method: group A (Classic toothbrush; Soft, Tepe, sweden) and group B (Superbrush toothbrush; Soft, Dentaco AS, Haukeland, Norway). **Setting and conduct:** A prophylaxis will be performed to achieve the plaque index of zero and then subjects are inhibited from doing any plaque control activity for 48 hours. Afterward the baseline plaque and bleeding point indices will be recorded and they will be given a common toothpaste (Crest). All participants will instruct to use both types of toothbrush for at least 3 minutes twice a day, using the Bass method without using dental floss. Each group will start the experiment with a different type of toothbrush for one week which will be followed by one week of washout. Then each group will switch to the next type of toothbrush for one week, and both plaque level and bleeding point indices will be recorded again with the same method, while the examiner is blind to trial type. **Participants including major eligibility criteria:** They are systemically healthy and able to attend for the period of the trial, having at least 20 natural teeth and not having orthodontic appliances or implants. **Intervention:** Using of the specified toothbrushes and not doing other oral hygiene procedures. **Main outcome:** Removing the plaque from the teeth.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015051517619N3**

Registration date: **2015-06-27, 1394/04/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-06-27, 1394/04/06

##### Registrant information

###### Name

Fereshteh Moosaali

###### Name of organization / entity

Kerman University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 1211 9023

###### Email address

moosaaly@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kerman university of medical sciences

##### Expected recruitment start date

2013-10-02, 1392/07/10

##### Expected recruitment end date

2013-11-05, 1392/08/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative evaluation of clinical efficacy of manual

Classic and manual Superbrush toothbrushes in plaque removing from the teeth surface of students

#### Public title

The efficacy of two manual toothbrushes on plaque and bleeding indices

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: Having at least 20 natural teeth.  
Exclusion criteria: Systemic disease that may effect the oral condition; caries; pregnancy; history of drug/alcohol abuse; smoking; presence of orthodontic appliances or implants; extensive restorations and periodontitis.

#### Age

From **19 years** old to **30 years** old

#### 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)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Crossover

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Kerman university of medical sciences

###### Street address

Kerman University of Medical Sciences, Shafa St.

###### City

Kerman

###### Postal code

##### Approval date

2013-09-23, 1392/07/01

##### Ethics committee reference number

K/92/178

### Health conditions studied

#### 1

##### Description of health condition studied

Plaque and bleeding point indices

##### ICD-10 code

K05.6

##### ICD-10 code description

Periodontal disease, unspecified

### Primary outcomes

#### 1

##### Description

Plaque index

##### Timepoint

1st day, 7th day and two week after intervention

##### Method of measurement

O`Leary plaque index

#### 2

##### Description

Bleeding point index

##### Timepoint

1st day, 7th day and two week after intervention

##### Method of measurement

Periodontal probe

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group 1: brushing with classic toothbrush. The Classic toothbrush is a simple, straight-forward toothbrush. When used twice daily as part of an overall oral hygiene regimen that includes between-teeth cleaning, the Classic toothbrush will help to take good care of dental health.

##### Category

Prevention

#### 2

##### Description

Intervention group 2: brushing with Superbrush toothbrush. Superbrush is a triple headed brush that cleans three surfaces of the teeth and gum margins simultaneously.

##### Category

Prevention

### Recruitment centers

#### 1

##### Recruitment center

**Name of recruitment center**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Abbas Pardakhti

**Street address**

Vice Chancellor for Research, Kerman University of Medical Sciences, Kerman, Iran.

**City**

Kerman

+98 34 3211 9023

**Fax****Email**

Sasan\_salahi@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Fereshteh Moosaali

**Position**

Periodontist and member of dental school

**Other areas of specialty/work****Street address**

Periodontology department, Dental faculty, Kerman University of Medical Sciences

**City**

Kerman

**Postal code****Phone**

+98 34 3211 9023

**Fax****Email**

moosaaly@kmu.ac.ir

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Abbas Pardakhti

**Street address**

Kerman University of Medical Sciences, Kerman, Iran.

**City**

Kerman

**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, Kerman 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**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Sasan Salahi

**Position**

Periodontist and member of dental school

**Other areas of specialty/work****Street address**

Periodontology department, Dental faculty, Kerman University of Medical Sciences, Shafa St., Kerman, Iran

**City**

Kerman

**Postal code****Phone****Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Fereshteh Moosaali

**Position**

Periodontist and member of dental school

**Other areas of specialty/work****Street address**

Periodontology department, Dental faculty, Kerman University of Medical Sciences

**City**

Kerman

**Postal code****Phone**

+98 34 3211 9023

**Fax****Email**

Moosaaly@kmu.ac.ir

**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*