

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

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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: $WI = (FLL - BLL) + (FFL - BFL) / BRL$ 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

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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.

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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

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Full name of responsible person

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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