

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Compare clinical efficacy of Hygen toothbrushes with and without battery in plaque removing from the teeth surface of students

#### Protocol summary

##### Summary

Objective: The purpose of this study was Comparing clinical efficacy of Hygen toothbrushes with and without battery in plaque removing from the teeth surface of students Design: In this clinical study, 40 students who are volunteers will be selected. Patients will be randomly divided into two groups with simple method, one group will be given toothbrushes with battery and the other group will be given toothbrushes without battery. Before brushing plaque will be measured and recorded. patients will brush a week then plaque will be measured and recorded and then the first toothbrush will be taken and second toothbrush will be given; the process will be repeated. In this regard, the biological samples will be taken before and after brushing. participants including major eligibility criteria:they are systemically healthy, are not smoker and pregnant (in women), Do not have orthodontic appliances, extensive restoration, or any device with brush interference , do not need to surgery in the oral cavity and they have the motivation and skills to participate in the study intervention: using of ionic toothbrushes with battery main outcome: removing plaque from the teeth surface

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201212174877N15**

Registration date: **2013-07-05, 1392/04/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-07-05, 1392/04/14

##### 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

2013-02-19, 1391/12/01

##### Expected recruitment end date

2013-03-19, 1391/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Compare clinical efficacy of Hygen toothbrushes with and without battery in plaque removing from the teeth surface of students

##### Public title

Compare clinical efficacy of Hygen toothbrushes in plaque removing from the teeth surface

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: systemically healthy, are not smoker and pregnant (in women). Do not have orthodontic appliances, extensive restoration, or any device with

brush interference . do not need to surgery in the oral cavity and they have motivation and skills to participate in the study

#### Age

From **20 years** old to **26 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **40**

#### 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 Isfahan University of Medical Sciences

##### Street address

Research vice chancellor, Dental School, Isfahan University of Medical Sciences, Hezarjerib avenue, Isfahan, Iran

##### City

Isfahan

##### Postal code

#### Approval date

2011-01-21, 1389/11/01

#### Ethics committee reference number

389464

## Health conditions studied

### 1

#### Description of health condition studied

Chronic gingivitis

#### ICD-10 code

K05.1

#### ICD-10 code description

Chronic gingivitis

### 2

#### Description of health condition studied

Chronic periodontitis

#### ICD-10 code

K05.3

#### ICD-10 code description

Chronic periodontitis

## Primary outcomes

### 1

#### Description

amount of microbial plaque

#### Timepoint

( before and 2 weeks after brushing)before and 2 weeks after intervention

#### Method of measurement

Microbial plaque measurement will be done before and after brushing with O'Leary index.

## Secondary outcomes

### 1

#### Description

Detection colony forming units

#### Timepoint

2 weeks

#### Method of measurement

Microbial assessment will be done for detection of colony forming units [CFU] from the plaque samples which will be collected with paper cone both before brushing and after brushing. The samples will be suspended in BPS and in order to transfer to culture

## Intervention groups

### 1

#### Description

Intervention1: using of ionic toothbrush with battery(hygen ionic, Hukuba Dental Corporation, Japan), twice a day, with bass technique

#### Category

Prevention

### 2

#### Description

Intervention 2: using ionic toothbrush without battery(hygen ionic, Hukuba Dental Corporation, Japan), twice a day, with bass technique

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Isfahan University of Medical Sciences- School of Dentistry

**Full name of responsible person**

Dr Jaber Yaghini

**Street address**

Department of Periodontology, School of Dentistry, Isfahan University of Medical Sciences, Hezarjerib avenue, Isfahan, Iran

**City**

Isfahan

Department of Periodontology, School of Dentistry, Isfahan University of Medical Sciences, Hezarjerib avenue, Isfahan, Iran

**City**

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**Postal code****Phone**

+98 93050508

**Fax****Email**

mozhgan.izadi.1165@gmail.com

**Web page address****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**

School of Dentistry, Isfahan University of Medical Science , Hezarjerib Avenue, Isfahan, Iran

**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 - School of Dentistry

**Full name of responsible person**

Dr Jaber Yaghini

**Position**

Assistant Professor

**Other areas of specialty/work****Street address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Department of Periodontology, School of Dentistry, Isfahan University of Medical Sciences

**Full name of responsible person**

Dr Jaber Yaghini

**Position**

Assistant Professor

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

Department of Periodontology, School of Dentistry, Isfahan University of Medical Sciences, Hezarjerib avenue, Isfahan, Iran

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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*