Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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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 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
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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
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
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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