Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation of clinical efficacy of an Iranian-made toothbrush in fixed orthodontic patients (Randomized clinical trial)

Protocol summary

Study aim

Determining the clinical efficacy of Confident toothbrush among fixed orthodontic patients

Design

Clinical trial, Cross over, Double blind, Randomized, Phase 3 on 40 patients, The rand function of the Excel software was used for randomization.

Settings and conduct

Two groups of 20 patients undergoing fixed orthodontic treatment are randomly selected. Plaque index (PI) , Gingival index(GI) and Ortho-plaque index(OPI) are measured for them at time T0. Patients are taught by a clinician how to brush.The first group uses an Iranian-made toothbrush (Confident), and the second group uses a common foreign brand (Oral B), and after one month (T1), all three indexes are measured. One-week washout period is located between two phase of the study and after one week at T2 all three indexes are measured again. The members of the two groups exchange, and finally, after a month, the indexes are measured at T3. The average of the indexes for patients in groups 1 and 2 is calculated at T0, T1, T2 and T3. Thus the clinical efficiency of this toothbrush is evaluated.

Participants/Inclusion and exclusion criteria

Patients are at the end of the first phase of treatment. Patients have a fixed orthodontic appliance for at least one month. Lack of lingual arch in the lower jaw and transpalatal arch or Nance in the upper jaw and any auxillary appliance.

Intervention groups

Patients in intervention group are asked to use Confident toothbrush and patients in control group are asked to use Oral B toothbrush for one month. Its efficacy is measured by comparing using Plaque index, Gingival index and Ortho-plaque index.

Main outcome variables

Plaque index (Silness & Loe): Microbial plaque thickness in the gingival area of the tooth to assess patient plaque control function. Gingival index (Silness & Loe): to assess the severity of gingivitis. Ortho-plaque index: Plaque index for fixed orthodontic patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200618047823N1**
Registration date: **2020-07-06, 1399/04/16**
Registration timing: **prospective**

Last update: **2020-07-06, 1399/04/16**
Update count: **0**

Registration date

2020-07-06, 1399/04/16

Registrant information

Name

Atefeh Barzegar sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

atefeh.sharifi1374@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-09, 1399/04/19

Expected recruitment end date

2020-07-30, 1399/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of clinical efficacy of an Iranian-made toothbrush in fixed orthodontic patients (Randomized clinical trial)

Public title
Evaluation of efficacy of an Iranian-made toothbrush in orthodontic patients

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients are 13-35 years old. Patients are at the end of the first phase of treatment. Patients have a fixed orthodontic appliance for at least one month. Patients are physically and mentally healthy in order to observe oral hygiene. Patient's consent to participate in the study and use of prescribed toothbrushes

Exclusion criteria:
Systemic disease History of antibiotic use over the past two months The presence of lingual arch in the lower jaw and transpalatal arch or Nance in the upper jaw and any auxillary appliance such as headgear, intrusion arch and ...

Age
From **13 years** old to **35 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done by Balanced block randomization. To randomize the samples, they are numbered in order of entry into the study, Randomization is done using 4 random blocks.Due to the fact that there are 2 different modes of 2 types of intervention, in each block 2 samples are assigned to each of the following states: 1. First Oral B then Confident 2. First Confident then Oral B The placement of samples inside the blocks will be by Random allocation method, in such a way that there are 2 samples from each group in the block. Randomization is done using Excel software and This process is designed by the project methodological consultant who is not involved in the executive operation of the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participant: The brand name of the toothbrush is covered. Care provider: The toothbrushes are distributed by another person and the person who measures indexes does not know how the participants are allocated in groups. Outcome assessor: The toothbrushes are distributed by another person and the person who gives patients information about oral hygiene and the method of brushing does not know how the participants are allocated in groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Dentistry school of Tehran University of Medical Science

Street address
N Kargar st.,Tehran University of Medical Sciences Faculty of Dentistry

City
Tehran

Province
Tehran

Postal code
300088351176

Approval date
2020-06-14, 1399/03/25

Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1399.029

Health conditions studied

1

Description of health condition studied
Evaluation of Plaque index (Silness & Loe), Gingival index (Silness & Loe) and Ortho-plaque index in fixed orthodontic patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Plaque index (Silness & Loe)

Timepoint
Measurement of Plaque index at the beginning of the study (before the start of the intervention) and 30, 37 and 67 days after the start of the study

Method of measurement
Disclosing tablets

2

Description
Gingival index (Silness & Loe)
Timepoint
Measurement of Gingival index at the beginning of the study (before the start of the intervention) and 30, 37 and 67 days after the start of the study
Method of measurement
Williams periodontal probe

3

Description
Ortho-plaque index
Timepoint
Measurement of Ortho-plaque index at the beginning of the study (before the start of the intervention) and 30, 37 and 67 days after the start of the study
Method of measurement
Disclosing tablets

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants use an Iranian toothbrush (Confident brand, with national standard mark, ISO 9001 certification and ISO 13485 certification) for one month, twice a day, 4 minutes each time, Modified bass method. All of them are taught by a clinician using a face-to-face dental model and instruction videos to brush the Modified bass method. Patients in both groups are advised to use the same interdental toothbrush, orthodontic floss, toothpaste and mouthwash. Also do not change them during the study period. At the beginning of the study and after one month, the Plaque index, Gingival index and Ortho-plaque index are measured using disclosing tablets (Made in USA). The clinical efficiency of the toothbrush is evaluated by comparing these indexes.
Category
Prevention

2

Description
Control group: Participants use Oral B toothbrush (Made in Ireland) for one month, twice a day, 4 minutes each time, Modified bass method. All of them are taught by a clinician using a face-to-face dental model and instruction videos to brush the Modified bass method. Patients in both groups are advised to use the same interdental toothbrush, orthodontic floss, toothpaste and mouthwash. Also do not change them during the study period. At the beginning of the study and after one month, the Plaque index, Gingival index and Ortho-plaque index are measured using disclosing tablets (Made in USA). The clinical efficiency of the toothbrush is evaluated by comparing these indexes.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran University of Medical Sciences Faculty of Dentistry
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100

Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Position
Assistant Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available