

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of plaque index and bleeding on probing scores in patient who use classic toothbrush and Salvadorapersica stick

Protocol summary

Study aim

The purpose of this study is to compare the anti-plaque property of miswak stick in comparison with classic toothbrush.

Design

Single-blind cross over randomized clinical trial. Sealed envelopes were used to randomize 16 volunteers (8 volunteers in each group).

Settings and conduct

Faculty of dentistry of Tehran university of medical sciences (TUMS) was considered as the study site. Both groups will be taught how to brush their teeth using the Rolling method. The first group will use miswak stick and the second group will use classic toothbrush for one week twice a day. After a week as wash out period, the volunteers will be transferred between groups. That is, the first group will use classic toothbrush and the second group will use miswak stick. On the 1st, 7th, 14th, and 21st days, an examination is performed to record the indicators of O'leary plaque and bleeding on probing (BOP).

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 20 to 35 years, presence of at least 20 teeth in occlusion, depth of the sulcus less than 3 mm, O'leary plaque index between 20 and 35 percent Exclusion criteria: systemic diseases, gingivitis and periodontitis, orthodontic appliance, restoration larger than usual (Overhang) or undesirable prostheses (Overcontour), motion and skill disorder, narcotic addiction, smoking, abnormal occlusion

Intervention groups

First group: using miswak stick Second group: using classic toothbrush

Main outcome variables

O'leary plaque index Bleeding on probing (BOP)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230514058179N1**
Registration date: **2023-06-15, 1402/03/25**
Registration timing: **prospective**

Last update: **2023-06-15, 1402/03/25**

Update count: **0**

Registration date

2023-06-15, 1402/03/25

Registrant information

Name

Atiyeh Khorram

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8800 4163

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-25, 1402/04/04

Expected recruitment end date

2023-07-11, 1402/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of plaque index and bleeding on probing scores in patient who use classic toothbrush and Salvadorapersica stick

Public title

Comparison between classic toothbrush and miswak stick

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 20 to 35 years Presence of at least 20 teeth in occlusion Depth of the sulcus less than 3 mm O'leary plaque index between 20 and 35 percent

Exclusion criteria:

Systemic diseases Gingivitis and periodontitis Orthodontic appliance Restoration larger than usual (Overhang) or undesirable prostheses (Overcontour) Motion and skill disorder Narcotic addiction Smoking Abnormal occlusion

Age

From **20 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization Randomization unit: individual Randomization tool: Sealed envelopes There is not allocation concealment. Sealed envelopes were prepared according to the number of people participating in the study, half of the envelopes were related to the A group and half were related to the B group. One of the envelopes will be randomly assigned to each participant.

Blinding (investigator's opinion)

Single blinded

Blinding description

Single blinded (clinical assessor has been blinded.)

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University Of Medical Sciences

Street address

Keshavarz Boulevard - Quds St. intersection

City

Tehran

Province

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Postal code

1417653761

Approval date

2023-01-22, 1401/11/02

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1401.134

Health conditions studied**1****Description of health condition studied**

Dental plaque

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Bleeding on probing

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

O'leary plaque index

Timepoint

At the beginning of the study (before the start of the intervention) and 7, 14 and 21 days after the start of the intervention

Method of measurement

The number of stained dental surfaces, with a disclosing agent (plaque detector tablet), divided by the number of teeth

2**Description**

Bleeding on probing (BOP)

Timepoint

At the beginning of the study (before the start of the intervention) and 7, 14 and 21 days after the start of the intervention

Method of measurement

By direct vision with a periodontal probe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Using a miswak stick in the first stage for one week and then using a classic toothbrush for a week in the second stage (after a one-week wash out stage between stages 1 and 2). At the beginning of the study (before the start of the intervention) and 7, 14 and 21 days after the start of the intervention, O'leary dental plaque indices and bleeding on probing (BOP) will be measured by the clinical examiner.

Category

Other

2

Description

Intervention group 2: Using a classic toothbrush in the first stage for one week and then using a miswak stick for a week in the second stage (after a one-week wash out stage between stages 1 and 2). At the beginning of the study (before the start of the intervention) and 7, 14 and 21 days after the start of the intervention, O'leary dental plaque indices and bleeding on probing (BOP) will be measured by the clinical examiner.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry of Tehran university of medical sciences

Full name of responsible person

Dr. Zeinab Kadkhoda

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North Kargar St. - faculty of Dentistry

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotuhi

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Tehran University of Medical Sciences, Quds Junc,

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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

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Atiyeh Khorram

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

Dr. Zeinab Kadkhoda

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Latest degree

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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

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Atiyeh Khorram

Position

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Latest degree

A Level or less

Other areas of specialty/work

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