

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 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)

##### Phone

+98 21 8800 4163

##### Email address

a.khoram92@gmail.com

##### 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**

Tehran

**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

#### Street address

North Kargar St. - faculty of Dentistry

#### City

Tehran

#### Province

Tehran

#### Postal code

1439955991

#### Phone

+98 21 8800 4163

#### Email

zkadkhoda@sina.tums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr. Akbar Fotuhi

#### Street address

Tehran University of Medical Sciences, Quds Junc,

Keshavarz Blvd

#### City

Tehran

#### Province

Tehran

#### Postal code

1439845773

#### Phone

+98 21 81631

#### Email

tumspr@tums.ac.ir

### 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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No. 113, Ebrahimi St. North Kargar St.

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#### Province

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Zeinab Kadkhoda

**Position**

professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Province**

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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**

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

**Street address**