

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### The effect of oral irrigator on periodontal indices in patients with generalized gingivitis

#### Protocol summary

##### Study aim

Study and comparison between effect of oral irrigator and dental floss as supplement of toothbrush on periodontal index at patients with gingivitis.

##### Design

Clinical trial with control group and parallel groups, single blind, randomized, phase 2 and 3 groups on 40 patients. A randomized table of numbers was used for randomization.

##### Settings and conduct

The study is located in periodontology department of Mashhad Dental School. In the intervention group, each participant will be given an oral irrigator(waterjet) and a toothbrush to compare the effect of waterjet on reducing gingival index, plaque index and bleeding on probe after 14 and 28 days. In the control group, each participant will be given toothbrushes and floss and after 14 and 28 days, we will measure the mentioned indicators. In this study, blinding was performed by using closed envelopes. The outcome stabilizer is not aware of the intervention method in the groups.

##### Participants/Inclusion and exclusion criteria

1.Generalized gingivitis. 2.Gingival index( Loe and Sillness Gingival Index ) 1 or more. 3.Bleeding on probing at more than 10 percent of teeth. 4.Participant not affected by systemic diseases associated with periodontal conditions. 5.Not pregnancy. 6.The patients without periodontal treatments within 1 month ago.

##### Intervention groups

In the intervention group, each participant will be given an oral irrigator(waterjet) and a toothbrush to compare the effect of waterjet on reducing gingival index, plaque index and bleeding on probing after 14 and 28 days. In the control group, each participant will be given toothbrushes and floss and after 14 and 28 days, we will measure the mentioned indicators.

##### Main outcome variables

Gingivitis; Plaque index; Oral health

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211221053478N1**

Registration date: **2022-07-27, 1401/05/05**

Registration timing: **prospective**

Last update: **2022-07-27, 1401/05/05**

Update count: **0**

##### Registration date

2022-07-27, 1401/05/05

##### Registrant information

##### Name

Sajjad Niroumand

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3880 0944

##### Email address

niroumands951@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-08-12, 1401/05/21

##### Expected recruitment end date

2022-09-12, 1401/06/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of oral irrigator on periodontal indices in patients with generalized gingivitis

**Public title**

The effect of oral irrigator on patients with gingival inflammation

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Generalized gingivitis Gingival index( Loe and Sillness Gingival Index ) 1 or more Bleeding on probing at more than 10 percent of teeth

**Exclusion criteria:**

Pregnancy The patients under periodontal treatments within 1 month ago Systemic diseases associated with periodontal conditions

**Age**

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: 40

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The patients were randomly assigned to the intervention and control groups by block randomization using a table of random numbers. Sealed envelop were used for allocation of random numbers to the patients.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The patients could not be blinded to the allocated procedure. However, the examiner who examine the plaque index, gingival index and bleeding on probing after the intervention was blinded to the group allocation of patients. Thus, the study had a single-blinded design. The statistician who analyzed the data was also blinded to the group allocation of patients.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Mashhad University of Medical

Science

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Beginning of Vakilabad Ave., In front of Mellat Park ., Mashhad Town

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**Postal code**

9177948959

**Approval date**

2021-12-01, 1400/09/10

**Ethics committee reference number**

IR.MUMS.DENTISTRY.REC.1400.118

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

Gingivitis

**ICD-10 code**

K05.10

**ICD-10 code description**

Chronic gingivitis, plaque induced

**Primary outcomes****1****Description**

Percentage of people with gingival index 1 or higher

**Timepoint**

Measurement of gingival index at the beginning of the study and 14 and 28 days after starting using dental floss and waterjet.

**Method of measurement**

Clinical examination and direct observation of gingival changes.

**Secondary outcomes****1****Description**

Bleeding on probing in more than 10 percent of teeth

**Timepoint**

Measurement of Bleeding on probing at the beginning of the study and 14 and 28 days after starting using dental floss and waterjet.

**Method of measurement**

Using the periodontal Williams probe

**2****Description**

Generalized or localized gingivitis.

**Timepoint**

Evaluation of gingivitis at the beginning of the study and 14 and 28 days after starting the use of dental floss and waterjet.

**Method of measurement**

Clinical examination and direct observation of gingival changes.

## Intervention groups

### 1

#### Description

Control group: After scaling patients' teeth, flossing (Mina brand) will be done twice a day for 4 weeks after brushing by people in the control group. Brushing will be done by Modified bass method and twice a day by Hi Dent brand manual toothbrush. The correct method of brushing and using dental floss will be taught by a trained evaluator.

#### Category

Treatment - Devices

### 2

#### Description

Intervention group: Oral irrigator will be used after brushing in the intervention group. The duration of using the device is twice a day for 4 weeks. Brushing will be done by Modified bass method and twice a day by Hi Dent brand manual toothbrush. The correct method of brushing and using oral irrigator will be taught by a trained dental student. Oral irrigator under the registered name (Waterjet mouth washer with the ability to monitor and control the user's hygienic behavior) has been designed and patented by a private Iranian company (registration number: 72641) ( patent number: 103383). Unlike other existing devices based on mechanical mechanisms and piston performance, this device has been designed and manufactured based on electromechanical system and on centrifuge performance. The power of spraying system is between 10 to 70 psi and beats from 100 to 1000 times per minute according to microcontroller programming. The liquid used in the oral irrigator is distilled water. The method of using oral irrigator in the intervention group is taught that the person places the tip of the device at an angle almost perpendicular to the surface of the teeth and supra gingival on the teeth after brushing by trained evaluator.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Dental university of Mashhad

**Full name of responsible person**

Majid Ghayour Mobarhan

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

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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**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Sajjad Niroumand

**Position**

Student  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Information about gingival indices will be accessible after indistinguishable to patients.

### When the data will become available and for how long

6 months after publishing the results

### To whom data/document is available

Researchers related to academic and scientific institutions

### Under which criteria data/document could be used

Only academic and scientific researchers will be allowed access to research data and can only be used for statistical analysis.

### From where data/document is obtainable

Applicants can receive data if they need the e-mail address of the author responsible for public accountability.

### What processes are involved for a request to access data/document

As the request, they will be answered by e-mail from the author responsible for public accountability within a month.

### Comments