

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

Street address

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

City

Mashhad

Province

Razavi Khorasan

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

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3882 9501

Fax

+98 51 3882 9500

Email

info@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour mobarhan

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3882 9501

Fax

+98 51 3882 9500

Email

info@mums.ac.ir

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
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
No. 197, Bahar3 Ave.,Bahar Blvd., Quchan Town
City
Quchan
Province
Razavi Khorasan
Postal code
9471644899
Phone
+98 51 4724 2091
Email
niroumands951@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Nava Naghibi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
No. 225, Resalat 9 Ave., Faramarz Blvd., Mashhad Town
City
Mashhad
Province
Razavi Khorasan
Postal code
9185775663
Phone
+98 51 3761 5597
Email
naghibin@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Sajjad Niroumand
Position
Student

Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
No. 197, Bahar3 Ave.,Bahar Blvd., Quchan Town
City
Quchan
Province
Razavi Khorasan
Postal code
9471644899
Phone
+98 51 4724 2091
Email
niroumands951@mums.ir

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